

JUDGE OETKEN

12 CIV 2237

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

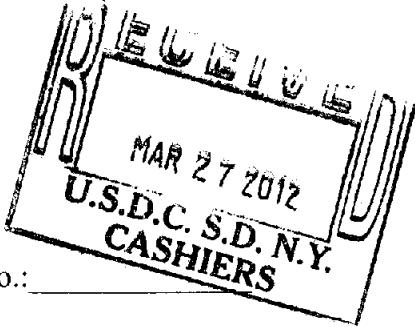
AMERICAN FEDERATION OF STATE,
COUNTY AND MUNICIPAL EMPLOYEES
DISTRICT COUNCIL 37 HEALTH &
SECURITY PLAN and SERGEANTS
BENEVOLENT ASSOCIATION HEALTH
AND WELFARE FUND, individually and on
behalf of all others similarly situated,

Plaintiffs,

v.

AMGEN, INC. and PFIZER, INC.,

Defendants.

Civil Action No.: 

**CLASS ACTION COMPLAINT
AND JURY DEMAND**

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I. INTRODUCTION

1. Plaintiffs American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan and Sergeants Benevolent Association Health and Welfare Fund bring this proposed class action against defendants Amgen Inc. and Pfizer, Inc. for their unlawful prescription co-payment (“co-pay”) subsidy programs. Defendants have paid, and continue to pay, undisclosed kickbacks to privately-insured individuals so that those health plan members will choose defendants’ branded drugs Celebrex, Chantix, Effexor XR, Enbrel, Geodon, Lipitor, Pristiq, and Sensipar, instead of less-expensive therapeutic alternatives. Defendants knowingly caused health benefit providers to pay for more prescriptions of these drugs than they would have, and caused falsely-inflated drug reimbursement rates to be reported to, and imposed on, members’ health benefit providers for these subsidized prescriptions.

2. Cost-sharing provisions in prescription drug benefit plans unite the financial interests of the health insurer with the interests of its beneficiaries. Requiring health plan members to pay a small portion of the high cost of a branded prescription drug — either a co-pay or co-insurance — provides a reasonable, personal incentive for privately-insured individuals to choose less-costly, usually generic, medications, and drives down the cost of the much larger residual portion paid by the health benefit providers.

3. In response to cost-sharing provisions, defendants began subsidizing members’ co-payments for their key brand name prescription drugs. These subsidies are designed to undermine cost-sharing arrangements. By eliminating or reducing member co-pays for branded drugs, plan members have no incentive to use less-expensive generic drugs, and health benefit providers end up paying for more costly branded drugs. A recent study estimated that these kickbacks will increase health benefit providers’ prescription drug costs by *\$32 billion* over the next ten years.

4. Each co-pay subsidy program is one size fits all, involving a formulaic, rote discount that applies regardless of the details of the patient's cost-sharing arrangements. Presenting a co-pay subsidy card to a pharmacist triggers a secondary form of insurance — provided by the manufacturer — that functionally reduces the price of the drug without disclosing that price reduction to the insurer. Each and every subsidy is calculated and processed electronically; the health benefit plans receive electronic records falsely indicating that the members paid their personal cost-share obligations, yet the manufacturer's digital paper trail discloses the truth — that the copayments were subsidized by the manufacturer.

5. DC 37, Sergeants, and the proposed classes allege two bases for defendants' liability. First, federal racketeering law prohibits this form of insurance fraud. Through agreements with servicing companies, defendants' routine waiver of co-payments means that the true cost for reimbursement of the routinely subsidized drugs are less than represented by the drug manufacturers and pharmacies, and thus the amount imposed on health benefit plans is inflated. The brand name defendants commit this fraud through their service providers, and the fraud is accomplished through the use of United States mail and wires. This suit seeks damages under 18 U.S.C. §1964(c) for violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1962 (c) and (d).

6. Second, federal antitrust law prohibits this form of commercial bribery. Under Section 2(c) of the Robinson-Patman Act, a seller cannot lawfully pay undisclosed kickbacks to someone who makes a decision to purchase a product that is paid for by another. 15 U.S.C. § 13(c). Defendants subsidize members' co-pays to induce them to purchase defendants' branded drugs instead of less-expensive therapeutic alternatives or AB-rated generic equivalents; health benefit providers then pay for the much more expensive branded drugs. Consumers who use

defendants' co-pay savings cards or coupons are not told that their insurers are paying more for defendants' brand-name drugs.

7. This suit seeks damages on behalf of classes of private health benefit providers under Section 4 of the Clayton Act (15 U.S.C. § 15) for overpayments caused by defendants' undisclosed kickbacks.

II. PARTIES

8. Plaintiff American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan ("DC 37") is based in New York and administers a variety of self-insured supplemental health and welfare benefits to its more than 125,000 members, which include current and retired employees of the City of New York and their dependents. DC 37's offerings include a prescription drug benefit. At all relevant times, DC 37's prescription drug benefit plan has contained cost-sharing provisions for plan members, provisions intended to place a personal financial obligation on the plan members through a tiered co-payment that places branded drugs in a less-preferred position than other commonly-prescribed therapeutic or AB-rated generic alternatives. During the course of defendants' subsidy schemes, DC 37 paid for much more expensive brand name drugs in circumstances where its members' cost-sharing obligations were not paid by them personally, but were subsidized by defendants. As a result of defendants' illegal subsidies, DC 37 purchased more of defendants' expensive brand name drugs than it otherwise would have. DC 37 was injured as a result of defendants' unlawful conduct.

9. Plaintiff Sergeants Benevolent Association Health and Welfare Fund ("Sergeants") is an employee welfare benefit plan located in the State of New York. Sergeants is a not-for-profit benefit fund that provides comprehensive health care benefits to approximately 12,000 active and retired New York City Police Department sergeants and their dependents. At all relevant times, Sergeants' prescription drug benefit plan has contained cost-sharing provisions

for plan members, provisions intended to place a personal financial obligation on the plan members through a tiered co-payment that places branded drugs in a less-preferred position than other commonly-prescribed therapeutic or AB-rated generic alternatives. During the course of defendants' subsidy schemes, Sergeants paid for much more expensive brand name drugs in circumstances where its members' cost-sharing obligations were not paid by them personally, but were subsidized by defendants. As a result of defendants' illegal subsidies, Sergeants purchased more of defendants' expensive brand name drugs than it otherwise would have. Sergeants was injured as a result of defendants' unlawful conduct.

10. Defendant Amgen Inc. ("Amgen") is a corporation organized and existing under the laws of the State of Delaware and has a place of business at One Amgen Drive, Thousand Oaks, California. Amgen markets the branded drug Sensipar, used to treat hyperparathyroidism in patients on dialysis. Amgen also jointly markets the branded drug Enbrel (etanercept injection), used to treat arthritis, with defendant Pfizer. From in or around 2006 through the present, Amgen and Pfizer subsidized privately-insured individuals' co-pays in order to increase the number of Enbrel and Sensipar prescriptions purchased by health benefit providers.

11. Defendant Pfizer, Inc. ("Pfizer") is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York. Pfizer markets the branded drugs Celebrex, Effexor XR, Chantix, Geodon, Lipitor, and Pristiq. Pfizer also markets Enbrel jointly with Amgen. Starting in or around 2006, Pfizer subsidized privately-insured individuals' co-pays in order to increase the number of Celebrex, Enbrel, Effexor XR, Chantix, Geodon, Lipitor, and Pristiq prescriptions purchased by health benefit providers.

12. TrialCard, Inc., located at 6501 Weston Parkway, Suite 370 in Cary, North Carolina, administers co-pay subsidy programs for Pfizer's Effexor XR and Lipitor. TrialCard advertises that it "provides branded Co-pay card programs that deliver an instant electronic rebate to a patient at the pharmacy, reducing out-of-pocket expense and equalizing tier position for [a manufacturer's] product." The company's website indicates that its co-pay program "[o]ffsets unfavorable tier/Co-pay position to level [the] playing field for patient out-of-pocket," and that one of its "client[s] reported [a return on investment] exceeding 600%."¹ TrialCard is *not* named as a defendant in this action but is an unnamed co-conspirator.

13. Pharmacy Data Management, Inc. ("PDMI"), located at 1170 East Western Reserve Road, Poland, Ohio 44514, administers co-pay subsidy programs for Pfizer's Celebrex, Chantix, Geodon, and Pristiq. On its website, PDMI claims that, "[t]o date, [it has] been able to accommodate all copay requests, including multi-tiered benefits."² PDMI is *not* named as a defendant in this action but is an unnamed co-conspirator.

14. McKesson Corporation, with headquarters at One Post Street in San Francisco, California, administers co-pay subsidy programs for Enbrel and Sensipar. McKesson's co-pay program, called LoyaltyScript, "serve[s] more than 17,000 patients every day" and has "saved patients more than \$335 million in out-of-pocket prescription costs."³ According to McKesson, the LoyaltyScript program allows manufacturers to "[i]ncrease market share through co-pay discounts that capture new customers" and "[g]ain valuable insight into program utilization to

¹ TrialCard Co-Pay Programs, <http://corpsite.trialcard.com/Pages/CoPayPrograms.aspx> (last visited Mar. 3, 2012).

² Benefits of Pharmacy Data Management, Inc., <http://www.pdmi.com/benefits.htm> (last visited Mar. 3, 2012).

³ McKesson Patient Relationship Solutions, http://sites.mckesson.com/mprs/solutions/loyalty_script_difference.shtml (last visited Mar. 3, 2012).

maximize your marketing ROI.”⁴ McKesson is *not* named as a defendant in this action but is an unnamed co-conspirator.

III. STANDING

15. Plaintiffs DC 37 and Sergeants have standing to bring this lawsuit for three independent reasons.

16. First, during the relevant time periods, and for each of the drugs and programs discussed below, DC 37 paid for prescriptions in circumstances where the defendants’ co-pay subsidies were not reflected in the overall reimbursement amount charged by the pharmacy and paid by DC 37. Sergeants, during the relevant time periods, paid for Celebrex and Lipitor prescriptions where defendant Pfizer’s co-pay subsidy was not reflected in the overall reimbursement amount charged by the pharmacy and paid by Sergeants.

17. Second, during the relevant time periods, and for each of the drugs and programs discussed below, DC 37 paid for prescriptions where the member’s co-pay was subsidized by defendants. Sergeants, during the relevant time periods, paid for Celebrex and Lipitor prescriptions where the member’s co-pay was subsidized by defendant Pfizer.

18. Third, during the relevant time periods, and for each of the drugs and programs discussed below, DC 37 paid for prescriptions that, but for defendants’ co-pay subsidies, would have otherwise been written for and filled with less expensive medications. Sergeants, during the relevant time periods, paid for Celebrex and Lipitor prescriptions that, but for defendant’s co-pay subsidies, would have otherwise been written for and filled with less expensive medications.

IV. JURISDICTION AND VENUE

19. This action arises under Section 4 of the federal RICO statute (18 U.S.C. §1964) and under section 2(c) of the Robinson-Patman Act (15 U.S.C. § 13), a 1936 amendment to the

⁴ *Id.*

Clayton Act (15 U.S.C. §§ 12-27); the Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question), 18 U.S.C. § 1964 (RICO), and 15 U.S.C. §15(a) (Robinson-Patman).

20. The activities of the defendants were within the flow of, were intended to, and did have a substantial effect on interstate commerce of the United States. Venue, therefore, lies within this District under 28 U.S.C. § 1391.

21. Venue is also proper under the special venue provisions of the federal racketeering and antitrust laws, 18 U.S.C. § 1965 and 15 U.S.C. § 22, as defendant Pfizer is headquartered in this District and both defendants transact business within this District.

V. FACTS

A. **Branded drug manufacturers have attacked the private prescription drug co-pay system.**

22. Branded drug manufacturers have attacked the private prescription drug co-pay system by subsidizing plan members' co-pays in order to undermine cost-sharing arrangements between health benefit providers and those they insure. These co-pay subsidy programs reduce or eliminate individuals' co-pays regardless of their financial need.⁵ Whether characterized as coupons, rebates, subsidies, or kickbacks, these payments to plan members interfere with health plans' cost-sharing provisions and intentionally influence prescription drug choices. The programs are designed, quite specifically, to reduce or eliminate privately-insured individuals' personal payment obligations so that they choose the brand name drug and their health benefit providers foot the bill.

23. Although co-pay subsidy programs vary as to the drugs covered and the specific amount of the subsidy or rebate, all programs work the same way. Individuals enroll in drug-

⁵ Co-pay subsidy programs are, by definition, primarily or exclusively for privately-insured individuals.

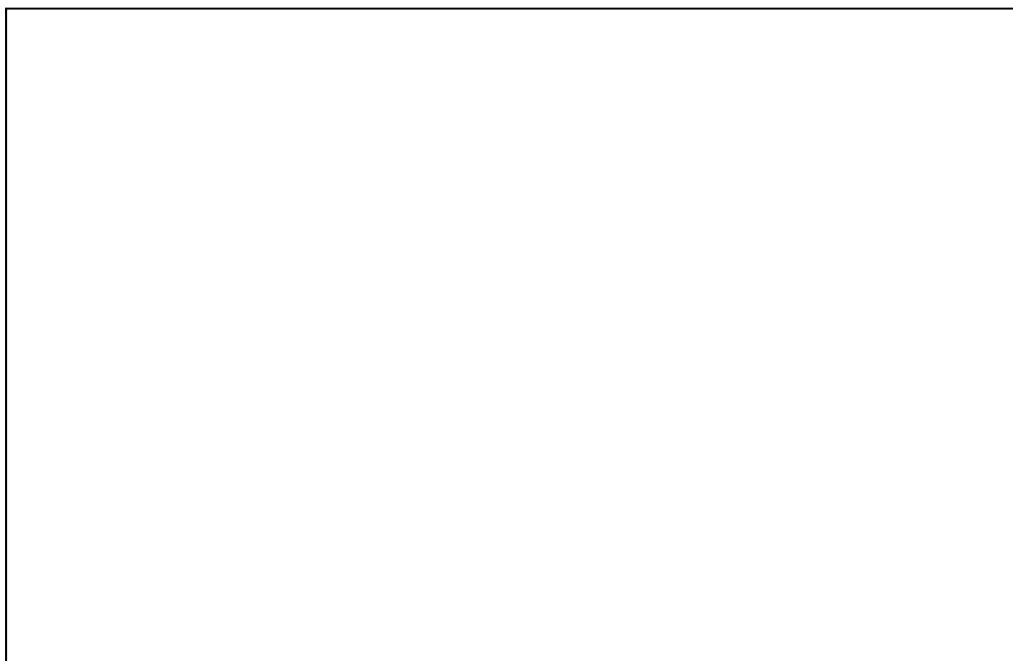
specific programs online.⁶ Individuals provide basic information (name, address, and whether they have private health insurance coverage) and the drug company mails them a wallet-size card that tells pharmacists how to process covered prescriptions. Some drug companies allow individuals to immediately print cards using their home computers.

24. Members then present their card at the pharmacy with a prescription, and the pharmacist processes the prescription according to the instructions on the card. The pharmacist enters information into a computerized data management system in order to submit a claim, first keying in the patient's health insurance information in the primary field. Insurance information regarding the transaction for that particular individual and his/her insurer is transmitted back to the pharmacist from the insurance company or its pharmacy benefit manager ("PBM"), including information about the member's co-pay or co-insurance obligation. The pharmacist then enters information from the co-pay card system into the secondary insurer field. Information regarding the extent of the co-pay subsidy or rebate is similarly computed, but only after the patient's primary insurance is processed (and billed).

25. The pharmacist and PBM use the reimbursement benchmark, which the brand name drug company provides to the reporting agency, to calculate the usual charge (*i.e.*, unreduced by the amount of the subsidy) to the health benefit insurer for the procurement of that prescription drug. The pharmacist and PBM do so without advising the insurer that, at the same time, the plan member's personal cost share obligation is being picked up by the drug's manufacturer. As a result, the private health benefit provider pays for the medication at its usual (but in fact now inflated) cost, and it does so without being told that the usual cost share obligation has not been paid by the enrollee, but rather by the brand manufacturer.

⁶ In the infancy of these programs, drug companies gave co-pay subsidy cards to doctors and pharmacists, who in turn gave the cards to patients. Some cards are still distributed this way, but most are available online.

26. In effect, defendants bribe plan members to choose their branded drugs over less-expensive therapeutic alternatives in order to get the health benefit plan to pay for the bulk of the cost of their more expensive branded drugs. From the member's perspective, the branded drug and generic alternatives cost close to, if not exactly, the same amount. But the price of the health benefit plan's share of the therapeutic alternative with the lower co-pay and the branded drug with the higher co-pay may differ by a factor of ten.



27. By their terms, defendants' co-pay subsidy programs (i) apply to individuals who are privately insured under a prescription drug plan that requires personal cost sharing by the member for retail prescription drugs such as those covered by the co-pay subsidy programs, (ii) undermine the contractual insurance arrangement between the insurer and the insurer's member by reducing or eliminating the personal cost-share feature of the insurance contract, (iii) cause the health benefit provider to pay for more units of expensive co-pay subsidy drugs than it would have if the defendants had not interfered with the parties' performance of the contract, and (iv) increase the overall burden of the plan in providing benefits to its members.

28. Co-pay subsidy programs are also effectively a form of secondary insurance, whereby defendants agree to cover a portion of the privately-insured individual's prescription drug expenses. Prescription drug benefit plans, along with the formularies under which they operate, set forth appropriate balances in coverage terms, means of access, payment obligations and cost-sharing provisions for medications. Prescription drug insurance contracts — whether they are wholly private plans or plans that are privately-administered but publicly subsidized (such as Medicare Part D plans or managed Medicaid drug plans) — are governed by myriad federal and state laws and regulations which ensure that the plans properly balance the availability of prescription drugs and sensible financial terms. Defendants' co-pay subsidies function as unregulated secondary health insurance that, after payment by the primary insurer, swoop in to relieve the plan member of specifically-designed *personal* financial obligations. By doing so, the co-pay card subsidy programs fundamentally change the nature of the regulated relationship between health insurers and members. Although defendants' co-pay subsidies function as a form of secondary insurance, defendants do not comply with the myriad laws governing the provision of health insurance.

B. Cost sharing is critical to the effective functioning of health care in the United States.

29. In most economic systems, the person who *selects* the product or service is also the person who *pays* for the product or service. Health care is a big, notable exception. Typically, a physician or other health care provider (in consultation with the patient) *chooses* the medication or medical procedure, the patient *receives* the care or consumes the medication, and a public or private health benefit provider *pays* for the services and medication. The payer is separated from those who make the purchasing decision. Without cost-sharing provisions — such as percentage co-insurance or graduated co-pays — those choosing the prescription drugs

(the patients in consultation with their physicians) have little or no incentive to choose less costly drugs.

30. Public and private health insurance relies on cost-sharing to re-align the interests of patients, health care providers, and health benefit providers. Although cost-sharing techniques vary by type and amount, they all have the singular purpose of imposing a personal financial obligation on the covered individual in order to encourage price sensitivity and achieve the range of acceptable balance between coverage and cost. Insured individuals often face point-of-service charges for medical services and prescription drugs. These include deductibles (amounts that must be paid before some or all services are covered), co-payments (fixed dollar amounts), and/or co-insurance (a percentage of the charge for services). Health benefit providers impose different degrees of cost sharing for different services: annual deductibles for medical services, a separate deductible for prescription drugs, hospital and outpatient co-insurance, co-pays for physician office visits, and/or out-of-pocket maximum amounts.

31. Cost sharing is therefore fundamental to almost all medical spending in the United States. Whether it be for hospital, physician, dental, or other health care provider services, for employer-sponsored or individual plans, for medical procedures, or for prescription drugs, numerous forms of cost sharing are imposed as a critical component of public and private health plans in order to carefully incentivize cost-conscious use of medical services and products while at the same time affording appropriate access to medical care.

C. The routine waiver of cost-sharing obligations, including co-payments and co-insurance, for medical services and products is unlawful.

32. Recognizing the ubiquity and necessity of cost sharing, federal and state statutes declare the practice of routinely waiving co-payment obligations for medical services and products to be unlawful.

33. First, routinely waiving co-pays constitutes financial inducements that are deemed illegal kickbacks. The waiver is in effect a form of payment that induces the use of medical services or products offered by the party that routinely waives co-pays. The routine waiver of co-pays amounts to health care fraud and is criminal.⁷ In the public arena, physicians, hospitals, and medical products providers who receive payment through Medicare or Medicaid programs and routinely waive co-payments or deductibles may be held in violation of federal and state anti-kickback statutes. The federal anti-kickback statute prohibits the payment of remuneration (any kickback, bribe or rebate) when it is knowingly paid to induce business that will be paid for by a federal health care program.⁸ And the routine waiver of co-payments in the Medicare and Medicaid areas forms the basis for a violation of the False Claims Act and the Civil Monetary Penalties Law.⁹

34. Second, the routine waiver of co-payments constitutes a form of insurance fraud.¹⁰ When cost sharing is routinely waived, the true acquisition cost for the medical service or product is not the stated or reported price being charged to health benefit providers, but rather the price *after deduction for the routinely waived co-payments*. The unlawfulness of this form of insurance fraud is well-known to physicians of any stripe, hospitals, and other health care

⁷ 18 U.S.C. § 1347: Health care fraud (“Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both. . . . [A] person need not have actual knowledge of this section or specific intent to commit a violation of this section.”); 18 U.S.C. § 1349: Attempt and conspiracy (“Any person who attempts or conspires to commit any offense under this chapter shall be subject to the same penalties as those prescribed for the offense . . .”).

⁸ 42 U.S.C. § 1320a-7b(b).

⁹ See 42 U.S.C. § 1320a-7a; 31 U.S.C. § 3729.

¹⁰ See, e.g., *Kennedy v. Connecticut Gen. Life Ins. Co.*, 924 F.2d 698, 699 (7th Cir. Ill. 1991) (appellant was required to collect co-payments from the insured patients if he wished to receive payment under an insurance plan that required co-payments: “Providers of medical care may seek to increase their business by promising to waive. . . co-payments. Patients prefer the lower outlays, but waivers annul the benefits of the co-payment system”); *id.* at 702 (“[a]llowing the provider to ‘pay’ the co-payment to himself is just another way to describe waiver of co-payments”).

providers. Physicians and other providers have been criminally prosecuted for routinely waiving co-payments yet still charging the insurer the inflated, pre-waiver price. The American Medical Association has long issued the following warning: “physicians should be aware that forgiveness or waiver of copayments may violate the policies of some insurers, both public and private. . . . Routine forgiveness or waiver of copayments may constitute fraud under state and federal law.”¹¹

35. Third, the terms of defendants’ co-pay subsidy programs would violate federal and state anti-kickback statutes. The federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)(2)) provides:

Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly . . . to any person to induce such person . . . to purchase . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program . . . shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

36. The Massachusetts False Health Care Claims Act (Mass. Gen. Laws 175H § 3) similarly provides:

[A]ny person who offers or pays any remuneration, including any bribe or rebate, directly or indirectly . . . to induce any person to purchase . . . any good, facility, service, or item for which payment is or may be made in whole or in part by a health care insurer, shall be punished by a fine of not more than ten thousand dollars, or by imprisonment in a jail or house of correction for not more than two and one-half years or in the state prison for not more than five years, or by both such fine and imprisonment, and may be held liable in a civil action.

37. Defendants knowingly offer and pay remuneration in the form of co-pay subsidies to patients in order to induce them to purchase defendants’ brand name drugs. The federal

¹¹ American Medical Association Opinion 6.12, issued June 1993, available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion612.page>.

government has acknowledged that co-pay subsidy programs may well violate the federal anti-kickback statute.¹²

38. Defendants know that subsidizing a co-payment for a drug paid for by the federal government or a Massachusetts resident would violate the statutes. Although defendants' programs purport to exclude Medicaid and Medicare recipients and Massachusetts residents in the fine print, on information and belief, the programs have been, and are being, used by persons who participate in those federal and state programs. For example, many individuals are enrolled in, and receive prescription drugs under Medicare Part D; but because Medicare Part D benefits are sponsored by private health benefit providers, individuals enrolling in defendants' programs may report themselves as privately insured, *not* as Medicare patients. Similarly, many Medicaid patients receive their care through managed Medicaid programs run by private health insurers, not state agencies; again, when enrolling in defendants' co-pay subsidy programs, these individuals may report themselves as privately insured simply by clicking the appropriate "no" buttons on defendants' websites.

39. If Medicare's ban on co-pay coupons were not enforced, costs to the Part D program would increase by \$18 billion over the period from 2012 to 2021.

40. Massachusetts is the only state that statutorily bans co-pay coupons for private payers. Were it to repeal that law, a recent study suggests that prescription drug costs for employers and other plan sponsors in Massachusetts would increase by \$750 million by 2021. Many states that do not explicitly prohibit these programs will see similar — or even larger — increases. For example, Illinois plans are expected to spend nearly \$1.4 billion extra on

¹² See Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70624 (Nov. 22, 2005) ("[W]e conclude that pharmaceutical manufacturer PAPs [Prescription Assistance Programs] that subsidize Part D cost-sharing amounts present heightened risks under the antikickback statute.").

prescription drug costs as a result of co-pay coupons or programs during that time; Florida, New York, California and Texas will spend an extra \$2 billion each in the next decade as a result of the same programs.¹³

D. Health benefit providers use cost sharing to cope with ever-increasing prescription drug costs.

41. Cost sharing has particular importance in the coverage for prescription drug benefits. In 2000, prescription drug spending in the U.S. exceeded \$142 billion. By 2009, spending ballooned to more than \$300 billion. This increase in drug spending is in large part due to high and rising prices for the most well-known and most often used brand name drugs. In recent years, the price of the most widely used brand name drugs increased annually at approximately 6% to 9% — two or three times the general rate of inflation. Each of the eight drugs at issue in this action has seen significant price increases in recent years.

1. Public and private health benefit providers use tiered cost sharing to reduce spending on prescription drugs.

42. For both public and private health benefit providers, prescription drug cost sharing is widely and effectively used, and has been for many years.

43. In the public realm, beneficiaries under Medicaid have, for years, been required to pay a portion of the cost of their medications despite the fact that Medicaid eligibility is limited to low income and disabled individuals. Similarly, even beneficiaries under Medicare Part B — generally the elderly receiving critical physician or in-home services — have been required to share the costs of their medications. And, more recently, beneficiaries under Medicare Part D

¹³ Visante, “How Copay Coupons Could Raise Prescription Drug Costs By \$32 Billion Over the Next Decade”, Nov. 2011, available at <http://www.pcmanet.org/images/stories/uploads/2011/Nov2011/visante%20copay%20coupon%20study.pdf> (“Visante Study”), at 13-15.

are required to make co-payment or co-insurance payments under terms specified by Medicare Part D plan sponsors.

44. Most health insurance in the United States is provided by private health benefit providers. In the private realm, cost sharing for prescription drugs is similarly widespread. Under private health insurance plans, individuals and employers pay premiums to health benefit providers and, in turn, the health benefit providers agree to pay all or a portion of the cost of needed medical services and products.¹⁴ Well over 95% of covered employees in employer-sponsored private health benefit plans have prescription drug benefits. More often than not, the form of cost sharing is a co-payment rather than co-insurance, although co-insurance has steadily increased over time.

45. Drug benefit cost-sharing provisions have evolved over the decades, with the key innovation being the differentiation of co-payments among differing drugs. When drug insurance was first introduced, the plan members typically paid the same coinsurance (or co-pay) rate for any drug. Over time, that changed and the price now depends on the “tier” in which the drug is placed. The early tiered plans typically had only two tiers, but most plans now have three or more tiers. In recent years, an increasing number of plans have created a fourth tier of drug cost sharing, which may be used for lifestyle drugs or expensive biologics:

¹⁴ In the United States, most private health insurance is paid at least in part by employers, although it is also common for employees to contribute to the cost of their premiums. Truly individual health insurance policies may also be purchased.

Generic drugs: A drug product that is no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies.

Preferred drugs: Drugs included on a formulary or preferred drug list; for example, a brand name drug without a generic substitute.

Non-preferred drugs: Drugs not included on a formulary or preferred drug list; for example, a brand name drug with a generic substitute.

Fourth-tier drugs: New types of cost-sharing arrangements that typically build additional layers of higher co-payments or co-insurance for specifically identified types of drugs, such as lifestyle drugs or biologics.

Brand name drugs: Generally, a drug product that is covered by a patent and is thus manufactured and sold exclusively by one firm. Cross-licensing occasionally occurs, which allow an additional firm to market the drug. After the patent expires, multiple firms can produce the drug product, but the brand name or trademark remains with the original manufacturer's product.

46. The number of plans requiring some form of cost sharing that differentiates between forms of drugs has steadily increased, but has plateaued in recent years. Almost 90% of privately-insured individuals have some formula for tiered cost-sharing; over 75% are enrolled in plans with three, four, or more tiers of cost sharing for prescription drugs.

47. A drug's tier placement largely depends on its cost: Tier 1 drugs are less expensive drugs, usually generic, drugs. More expensive, usually brand name, drugs are placed on higher tiers. Health benefit providers encourage members to choose Tier 1 drugs by imposing a lesser co-pay than that imposed for Tier 2 drugs. Tiered co-payments and co-insurance (which is a percentage of the overall cost of the drug at retail) thereby provide reasonable personal financial incentives to individuals to use equally effective but less costly medications. If a drug is placed on Tier 1, the customer pays the pharmacy a relatively small co-payment. If the drug is placed on Tier 2, the co-payment or coinsurance obligation increases. The difference in the co-payment/coinsurance between Tier 2 and Tier 1 incentivizes the plan member to choose the less

costly medication. If a drug is a Tier 3 drug, a therapeutic or generic equivalent will invariably exist for the medication in Tier 2 and/or Tier 1.

48. Another major, long-term trend has been the increasing *amount* of the co-payment or coinsurance required. Over the last decade, average retail co-payment levels increased by about 62%. Average co-payments for Tier 2 drugs increased by about 127%. Average co-payments for Tier 3 drugs increased the most, from about \$17.53 in 1998 to about \$42.95 in 2009, an increase of about 149%. As expected, the 2009 average retail co-payment for Tier 4 drugs is even greater, at \$62.11.

49. Widespread use of cost sharing for prescription drugs, the increasing trend of multi-tier cost sharing and the increasing amounts for co-payments and co-insurance are, of course, no accident. Although other forms of prescription drug cost reductions may have more dramatic results — including the market entry of AB-rated generic equivalents — cost sharing has defined measurable results. Cost sharing provides personal financial incentives to plan members to select the most cost-appropriate medications; these incentives work.

50. Patients — and to a lesser extent, their doctors — are sensitive to differences in co-payment requirements, particularly for maintenance drugs they anticipate taking for a long or indefinite periods of time. According to a 2007 literature review published in the Journal of the American Medical Association, *every 10% increase in cost sharing (through co-payments or co-insurance) reduces drug spending by 2 to 6%*. And drug companies are well aware that plan members' consider co-pay differences when choosing prescription drugs: “[t]he patient, I will tell you, is economically very, very sensitive to co-pays, and a \$5, \$10, \$20, \$25 co-pay matters,” says Abbott Laboratories Chief Executive Miles White.¹⁵

¹⁵ Event Brief of Q2 2009 Abbott Earnings Conference Call – Final, FD (Fair Disclosure) Wire (July 15, 2009).

2. Branded drugs are expensive; differentiated cost-sharing for branded and generic drugs help health benefit providers and health plan members curtail prescription drug spending.

51. Generic drugs thus play a critical role in health benefit providers' attempts to curb ever-escalating prescription drug costs. Generic drugs are almost always significantly less expensive than their branded counterparts. On average, generic prescriptions cost payers \$16, preferred brand prescriptions cost \$118, and non-preferred brands cost \$124. Tiered cost-sharing provisions thus incentivize generics by imposing a lower co-pay or co-insurance for generics than for brands.

52. AB-rated generics are, by definition, substitutable for their branded equivalents. All fifty states have laws that permit pharmacies to substitute AB-rated generics for their branded counterparts when an AB-rated equivalent is available. Health benefit providers create strong incentives for plan members to demand generic drugs by imposing different co-pays for branded and generic drugs. Consequently, more than 90% of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. 2010 IMS industry data — the industry's gold standard — reflects that, on average, AB-rated generics capture 80% of the brand's sales within the first six months.

53. In addition to AB-rated generics, a brand name drug may also have generic therapeutic alternatives. Therapeutic alternatives are *not* bioequivalent to their brand-name counterparts, but are alternative medicines that treat the same medical condition in a similar way. As an example, Pfizer's blockbuster drug Lipitor belongs to a therapeutic class of drugs called "statins" used to treat high cholesterol. But because statins work in similar ways, a patient and/or physician may determine that another statin, such as generic simvastatin, lovastatin, and pravastatin, is a sensible cost-effective alternatives — particularly since (without a co-pay

subsidy) the cost to the patient by reason of the tiered co-payment system would be much higher for Lipitor than for a generic statin.

E. Co-pay subsidies work: health plan members fill prescriptions for branded drugs instead of generics and health benefit providers pay much higher prices for the subsidized prescriptions.

54. These kickbacks work. According to a 2011 study undertaken for the Pharmaceutical Care Management Association and based on evidence from drug coupon administrators, “25% of [co-pay] coupon use results in a couponed drug being used instead of a preferred brand or generic that might have been used in the absence of the coupon.”¹⁶ More than 100 million prescriptions were associated with co-pay coupons in 2010, accounting for 11% of brand prescriptions.¹⁷ These numbers will grow exponentially: at current trends, the number of prescriptions associated with co-pay subsidy programs will increase by 15% per year, reaching 500 million prescriptions and approximately 50% of non-specialty brand prescriptions by 2021.¹⁸ All told, employers and other plan sponsors will likely spend an extra \$32 billion on prescription drugs as a result of these co-pay subsidy programs over the next decade.¹⁹

55. It is estimated that pharmaceutical companies spend \$4 billion on co-pay cards and coupons annually.²⁰ Drug manufacturer Amgen has stated publicly that spending on its co-pay subsidy programs amounts to about *1% of its total product sales*; in the first quarter of 2010, Amgen spent \$35 million on co-pay subsidy programs. This amount is likely to increase as more co-pay programs are created and more plan members take advantage of existing programs.

¹⁶ Visante Study, at 11.

¹⁷ *Id.* at 12.

¹⁸ *Id.*

¹⁹ *Id.* at 3, 13-15.

²⁰ Matthew Herper, *How Bargain Lipitor Could Raise Health Costs*, FORBES.COM, <http://blogs.forbes.com/matthewherper/2011/03/16/how-bargain-lipitor-could-raise-health-costs/> (last visited Mar. 2, 2012) (citing Mason Tenaglia, managing director of the Amundsen Group, a consulting firm that has studied the cards). See also Visante Study at 6.

56. Brand-name pharmaceutical manufacturers know that these co-pay subsidy programs work: these programs are now a regular part of life cycle planning for branded drugs typically launching two to three years before AB-rated generic equivalents of the brand name drug are expected to enter the market. The manufacturer tries to maximize the number of prescriptions written by physicians, filled by members, and paid for by both members and health benefit providers before pharmacies begin automatically substituting the AB-rated generic equivalents for the brand name drug.

57. Health benefit providers have seen significant increases in the number of prescriptions filled for brand name drugs that have co-pay subsidy programs. Recently, co-pay subsidy administrators have anecdotally reported that their unnamed clients, manufacturers of branded drugs, earn between a 4:1 and 6:1 return on their investments in these programs.

58. The attack on prescription drug co-payment system is open and notorious. Large branded drug companies reflexively subsidize co-payments for many brand name drugs simply because they are nearing patent expiry. Co-payment subsidy administration has become a cottage industry. Program administrators boast about the effective and efficient methods by which they have wiped out the personal financial incentives of plan enrollees to select, in consultation with their physicians, less costly medications.

59. Drug companies, including defendants, not only determine the price at which wholesalers or large retailers will purchase prescription drugs from them, but also control the reimbursement benchmark used to determine the amount to be paid for the drugs by public and private health benefit providers. Either by directly determining the so-called average wholesale price (or “AWP”) or by determining a related price benchmark known as the wholesale acquisition price (or “WAC”) that reporting agencies use to mathematically determine the AWP,

branded drug manufacturers cause to be published the widely-used and nearly ubiquitous benchmark prices for payments and reimbursements that health benefit providers make to pharmacies for branded, retail-channel drug products.

60. Branded drug manufacturers, including defendants, know that the reported benchmark that they control is required to be a reasonably fair estimation of the actual price for the ingredient cost of the drug to the retailer. When a prescription for a privately-insured individual is filled at the retail level (*i.e.*, a pharmacy), the pharmacy charges the member's plan for the ingredient cost of the drug plus a dispensing fee. The amount to be charged for the ingredient cost is based on a percentage discount from the benchmark (*e.g.*, AWP minus 14% for all branded drugs). Thus, the stated benchmark represents the price that all participants — the health benefit provider, its pharmacy benefit manager, the pharmacy and the manufacturer — understand is a reasonable estimate of the actual cost to the pharmacy on which the payer's reimbursement to the pharmacy is based. Of course, if a cost-sharing provision exists for the member's prescription drug plan, then the cost share (*e.g.*, co-payment or co-insurance) is deducted from the amount owed by the plan to the pharmacy, and imposed on the member as a payment to the pharmacy. However, for subsidized co-pays the true benchmark is less, resulting in an inflated payment by the health insurers.

61. Routinized co-pay subsidy programs constitute commercial bribery because the programs pay undisclosed kickbacks to plan enrollees to select expensive medications that are paid for by prescription drug benefit providers.

62. Routinized co-pay subsidy programs constitute insurance fraud because routine waiver of co-payments reduces true acquisition costs, yet drug manufacturers withhold co-

payment information, do not decrease the applicable reimbursement benchmark for the drug, and cause inflated payments to be imposed upon private prescription drug benefit providers.

F. Defendants Amgen and Pfizer subsidized health plan members' co-pays for Celebrex, Chantix, Effexor XR, Enbrel, Geodon, Lipitor, Pristiq, and Sensipar.

63. Defendants designed and implemented the programs described below (collectively, the "co-pay subsidy programs"), relating to the brand name drugs Celebrex, Chantix, Effexor XR, Enbrel, Geodon, Lipitor, Pristiq, and Sensipar (collectively, the "co-pay subsidy drugs").

64. Each of defendants' co-pay subsidy programs described below alters the carefully calibrated co-payment system negotiated by health benefit providers and their members. Each is intended to steer unsuspecting members toward more expensive brand name drugs when less expensive therapeutic alternatives are available in generic form, with generic price tags.

1. Pfizer's Celebrex Savings Card

a. Pfizer faced substitution competition from less-expensive therapeutic alternatives to Celebrex

65. On December 31, 1998, the FDA approved Celebrex (celecoxib) to treat the signs and symptoms of osteoarthritis (a condition in which inflammation of the joints results in pain and degeneration) and rheumatoid arthritis (an autoimmune disease in which the immune system attacks the joints).

66. Over 46 million Americans suffer from arthritic symptoms, and the pharmaceutical market for arthritis generated \$15.9 billion in revenues in 2008 alone. In 2010, sales of Celebrex alone were over \$1.3 billion.

67. Less expensive therapeutic alternatives to Celebrex include prescription ibuprofen.

68. In 2009, Pfizer executives told investors that, for drugs like Celebrex, which were facing “a reasonably generitized market with managed care pressure and co-pays,” the company was focused on, among other things, “using co-pays to try and offset the managed care tiering.”²¹

b. In the wake of substitution competition from less expensive therapeutic alternatives, Pfizer created the Celebrex Savings Card.

69. To stave off substitution competition from less expensive therapeutic alternatives, in or around 2007, Pfizer created the Celebrex Savings Card.

70. Through the Savings Card, Pfizer pays up to \$15 of a patient’s co-pay. Although the terms and conditions governing the Savings Card used to limit patients to six prescriptions per year (\$90 per year), this changed in or around early 2012, and Pfizer now pays up to \$15 of a patient’s co-pay for up to \$180 per year (or, twelve prescriptions). Anyone can sign up for the Celebrex Savings Card via Pfizer’s website, <http://www.celebrex.com/offers.aspx>. A patient eighteen years of age or older can print and activate a Celebrex Savings Card by entering his or her name, address, e-mail address, and agreeing to Pfizer’s Privacy Statement.

71. According to Pfizer’s website, the Celebrex Savings Card will expire on December 31, 2012.

72. The Celebrex Savings Card is not a need-based program. It is open to all patients with a prescription for Celebrex, and it subsidizes the co-pays of any commercially-insured patients.

The Celebrex Savings Card specifically provides that it does not apply to Medicare or Medicaid patients or to residents of Massachusetts.

73. The “Eligibility Requirements” for the Celebrex Savings Card specifically exclude Medicare or Medicaid patients and commercially-insured residents of Massachusetts:

²¹ Ian Read, President, Pfizer’s Global Pharmaceutical Operations, *Q2 2009 Pfizer Earnings Conference Call – Final*, FD (Fair Disclosure) Wire (July 22, 2009).

Eligibility Requirements

1) The Card is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare, or other federal or state healthcare programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico [formerly known as “La Reforma de Salud”] . . . 6) The Card is not valid for Massachusetts residents whose prescriptions are covered in whole or in part by third-party insurance, or where otherwise prohibited by law.

d. The Celebrex Savings Card functions as an unlawful form of secondary health insurance.

74. The fine print accompanying the Celebrex Savings Card instructs pharmacies to process it after the patient’s primary insurance is processed, just as a claim for secondary health insurance would be processed.

To the Pharmacist:

For patients with CELEBREX coverage: Use your customer’s prescription insurance for the primary claim. Process a Coordination of Benefits claim to PDMI under BIN: 610020 as the secondary claim.

For patients without CELEBREX coverage: Process a primary claim to PDMI under BIN: 610020.

e. Pfizer knows that third party payors cannot tell when a co-pay is subsidized.

75. Pfizer knows that the Celebrex co-pay subsidy program that Pfizer and its coupon administrator have designed makes it impossible for third party payors to tell if their members’ co-pays are being subsidized by coupons. Pfizer admits as much in the fine print that accompanies the coupon, where it attempts to push onto patients the responsibility for making such disclosures: “You must deduct the value received under this program from any reimbursement request submitted to your insurance plan, either directly by you or on your behalf.” By burying a disclosure like this in a sea of fine print, Pfizer makes a weak attempt to shield itself from liability with instructions it knows and intends will not be seen or followed.

- Bring your CELEBREX prescription and the entire Savings Card PDF to a participating pharmacy.
- Use your Savings Card for up to 6 CELEBREX purchases through December 31, 2011.*

Download CELEBREX Savings Card

Don't have a PDF viewer? [Get one now from Adobe®.](#)

Eligibility Requirements

- 1) The Card is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare, or other federal or state healthcare programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico [formerly known as "La Reforma de Salud"]). 2) The Card is not valid for prescriptions that are eligible to be reimbursed by private insurance plans or other health or pharmacy benefit programs which reimburse you for the entire cost of your prescription drugs. **3) You will receive up to \$15 off or the amount of the co-pay you paid, whichever is less. 4) This Card is good for up to \$90 per calendar year.** 5) You must deduct the value received under this program from any reimbursement request submitted to your insurance plan, either directly by you or on your behalf. 6) The Card is not valid for Massachusetts residents whose prescriptions are covered in whole or in part by third-party insurance, or where otherwise prohibited by law. 7) Cannot be combined with any other rebate/coupon, free trial, or similar offer for the specified prescription. **8) The Card will be accepted only at participating pharmacies. 9) This Card is not health insurance.** 10) Offer good only in the U.S. and Puerto Rico. 11) The Card is limited to 1 per person during this offering period and is not transferable. 12) Pfizer reserves the right to rescind, revoke, or amend the program without notice. 13) No membership fees. 14) Card and Program expire 12/31/11.

For reimbursement when using a nonparticipating pharmacy/mail order: Pay for CELEBREX prescription and mail copy of original pharmacy receipt (cash register receipt NOT valid) with product name, date, and amount circled to: CELEBREX Savings Card, 6501 Weston Parkway, Suite 370, Cary, NC 27513. Be sure to include a copy of the front of your Savings Card, your name, and mailing address.

NEXT: Taking CELEBREX ➤

2. Pfizer's Chantix Coupon

a. Pfizer faced competition from less expensive therapeutic alternatives to Chantix.

76. On May 10, 2006, the FDA approved Chantix (varenicline tartrate) as a treatment to aid smoking cessation. A year after its launch, more than 3.5 million smokers had been prescribed Chantix. Pfizer launched a branded advertising campaign to build on this momentum.²²

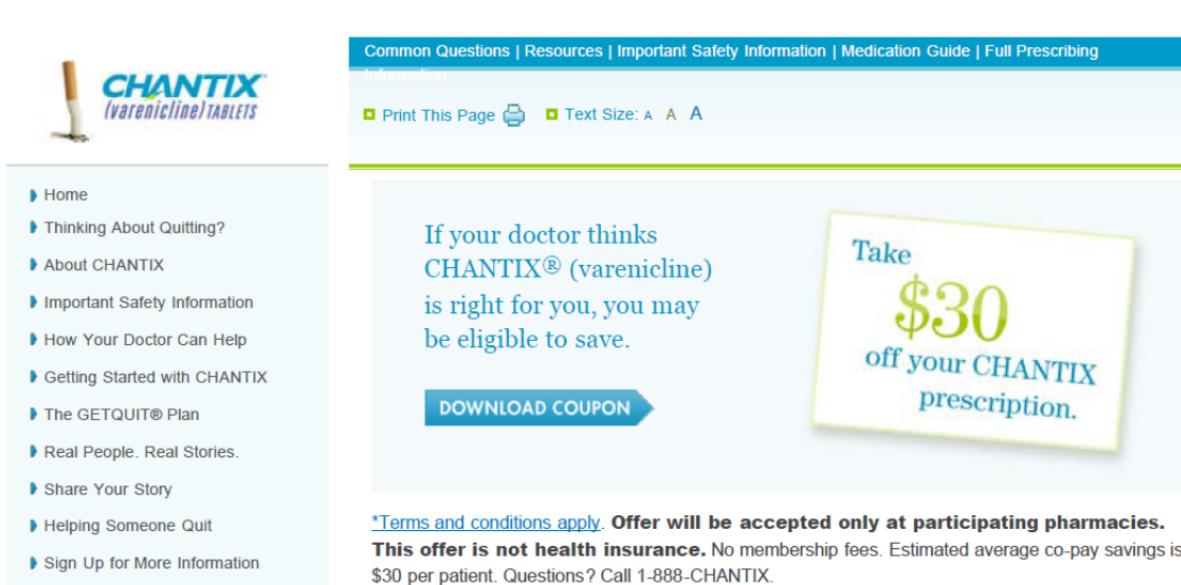
²² Jeff Kindler, Chairman and CEO, Pfizer, *Q3 2007 Pfizer Earnings Conference Call – Final*, FD (Fair Disclosure) Wire (Oct. 18, 2007).

77. By mid-2008, sales of Chantix were down after Pfizer was required to update the products' labeling to include additional safety warnings.²³ Ian Read, President of Pfizer's Worldwide Pharmaceutical Operations, noted that the company was also seeing "a slow-up in the US market growth rate" for Chantix due to higher co-pays.²⁴

78. Less expensive therapeutic alternatives to Chantix include bupropion (Zyban).

b. In the wake of substitution competition from less expensive therapeutic alternatives, Pfizer introduced the Chantix Coupon.

79. To combat the substitution competition it was facing from less expensive therapeutic alternatives, in or around 2008, Pfizer created the Chantix Coupon. In February 2010, the coupon was made available on Pfizer's website.²⁵



The screenshot shows a web page for Chantix (varenicline) tablets. At the top, there is a navigation bar with links to 'Common Questions', 'Resources', 'Important Safety Information', 'Medication Guide', and 'Full Prescribing Information'. Below the navigation bar, there are two buttons: 'Print This Page' and 'Text Size: A A A'. On the left side, there is a sidebar with a list of links: Home, Thinking About Quitting?, About CHANTIX, Important Safety Information, How Your Doctor Can Help, Getting Started with CHANTIX, The GETQUIT® Plan, Real People. Real Stories., Share Your Story, Helping Someone Quit, and Sign Up for More Information. The main content area features a message: 'If your doctor thinks CHANTIX® (varenicline) is right for you, you may be eligible to save.' Below this message is a blue button labeled 'DOWNLOAD COUPON'. To the right of the message, there is a graphic with the text 'Take \$30 off your CHANTIX prescription.' At the bottom of the page, there is a note: '*Terms and conditions apply. Offer will be accepted only at participating pharmacies. This offer is not health insurance. No membership fees. Estimated average co-pay savings is \$30 per patient. Questions? Call 1-888-CHANTIX.'

²³ Frank D'Amelio, CFO & Senior Vice President, Pfizer. *Q2 2008 Pfizer Earnings Conference Call – Final*, FD (Fair Disclosure) Wire (July 23, 2008).

²⁴ *Id.*

²⁵ Chantix Offers, <http://www.chantix.com/offers.aspx> (last visited Mar. 6, 2012).

80. When patients click the “Download Coupon” button on the website, they can immediately print a coupon for \$30 off of their Chantix prescription, or the amount of their copay, whichever is less:



81. The coupon is limited to one per person during the offering period, which ends December 31, 2012.

82. Pfizer’s Chantix Coupon is not a need-based program. It is open to all patients with a prescription for Chantix, and it subsidizes the co-pays of any commercially-insured patients. A patient can download and print the coupon from Pfizer’s website (<http://www.chantix.com/get-coupon-pdf.aspx>) without entering any personal information.

83. The Chantix Coupon is advertised directly to patients on national television. For example, a ninety-second commercial aired on the Arts & Entertainment cable television network on September 12, 2011 concludes by saying, “Learn how you can save money and get terms and conditions at Chantix.com” while the screen displays the text “Money-saving Offer Now Available.”

c. **The Chantix Coupon specifically provides that it does not apply to Medicare or Medicaid patients or to residents of Massachusetts.**

84. Pfizer's website outlines the Terms and Conditions governing the use of the Chantix Coupon. Medicare or Medicaid patients and residents of Massachusetts are clearly excluded:

Terms and Conditions

By using this coupon, you acknowledge that you currently meet the eligibility criteria and will comply with the terms and conditions described below:

This coupon is *not* valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare, or other federal or state healthcare programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico [formerly known as "La Reforma de Salud"]). . . . This coupon is not valid for Massachusetts residents whose prescriptions are covered in whole or in part by third-party insurance, or where otherwise prohibited by law.

d. **The Chantix Coupon functions as an unlawful form of secondary health insurance.**

85. The fine print on Pfizer's website states that the Chantix Coupon "is not health insurance," but the message to pharmacists that is printed on the coupon provides the following instructions:

To the Pharmacist:

For Patients with CHANTIX coverage:

Use your customer's prescription insurance for the primary claim. Process a Coordination of Benefits claim to PDMI under Bin: 610020 as the secondary claim.

For patients without CHANTIX coverage:

Process a primary claim to PDMI under BIN: 610020.

Despite Pfizer's disclaimer in the fine print on its website, the coupon functions as a form of secondary insurance.

e. **Pfizer knows that third party payors cannot tell when a co-pay is subsidized.**

86. Pfizer knows that the Chantix co-pay subsidy program that Pfizer and its coupon administrators have designed makes it impossible for third party payors to tell if their members' co-pays are being subsidized by co-pay coupons. Pfizer admits as much in the fine print of the Chantix Coupon's Terms and Conditions, where it attempts to push onto patients the responsibility for making such disclosures: "You must deduct the value of this coupon from any reimbursement request submitted to your insurance plan, either directly by you or on your behalf." By burying this disclosure in the fine print of the coupon's Terms and Conditions, however, Pfizer makes a weak attempt to shield itself from liability with instructions it knows and intends will not be seen or followed.

Before starting CHANTIX, tell your doctor if you are pregnant, plan to become pregnant, or if you take insulin, asthma medicines, or blood thinners. Medicines like these may work differently when you quit smoking.

Terms and Conditions

By using this coupon, you acknowledge that you currently meet the eligibility criteria and will comply with the terms and conditions described below:

This coupon is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare, or other federal or state healthcare programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico [formerly known as "La Reforma de Salud"]). This coupon is not valid for prescriptions that are eligible to be reimbursed by private insurance plans or other health or pharmacy benefit programs that reimburse you for the entire cost of your prescription drugs. Coupon is limited to \$30 or the amount of your co-pay, whichever is less. No membership fees. You must deduct the value of this coupon from any reimbursement request submitted to your insurance plan, either directly by you or on your behalf. This coupon is not valid for Massachusetts residents whose prescriptions are covered in whole or in part by third-party insurance, or where otherwise prohibited by law. Coupon cannot be combined with any other rebate/coupon, free trial, or similar offer for the specified prescription.

This coupon will be accepted only at participating pharmacies. This coupon is not health insurance. Offer good only in the US and Puerto Rico. Coupon is limited to 1 per person during this offering period and is not transferable. Pfizer reserves the right to rescind, revoke, or amend this offer without notice. For reimbursement when using a non-participating pharmacy/mail order: Pay for the CHANTIX prescription and mail copy of original pharmacy receipt (cash register receipt NOT valid) with product name, date, and amount circled to: CHANTIX Savings Program, 6501 Weston Parkway, Suite 370, Cary, NC 27513. Be sure to include a copy of this page, your name, and your mailing address. Offer expires 12/31/2011.

Please see full prescribing information and patient Medication Guide on the following pages.



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Pfizer, PO Box 29387, Mission, KS 66201

VCP02614/291202-01

www.chantix.com

3. Pfizer's Effexor XR \$4 Co-Pay Commitment Program

a. **Pfizer faced competition from less expensive therapeutic alternatives after the launch of Effexor XR.**

87. On October 20, 1997, the FDA approved Effexor XR (venlafaxine hydrochloride) to treat depression. By 2008, sales of Effexor XR had topped \$2.6 billion.

88. Less expensive therapeutic alternatives to Effexor XR include selective serotonin reuptake inhibitors (SSRIs) – such as sertraline (Zoloft), citalopram (Celexa), bupropion XL (Wellbutrin XL), fluoxetine (Prozac)) and selective serotonin norepinephrine reuptake inhibitors (SNRIs) – such as instant release venlafaxine (Effexor)).

b. In the wake of substitution competition from less expensive therapeutic alternatives, Pfizer created the Effexor XR \$4 Co-Pay Commitment Program.

89. To combat the substitution competition it was facing from less expensive therapeutic alternatives, in or around April 15, 2010, Pfizer created the Effexor XR \$4 Co-pay Commitment Program. Pfizer's website invites patients to register for the program and receive a savings card that they can present to pharmacies to receive Effexor XR for as little as a \$4 co-pay (up to \$75 off per refill, or a maximum of \$1000 per calendar year).²⁶

The screenshot shows a green header bar with navigation links: "About EFFEXOR XR", "Depression", "Anxiety Disorders", and "\$4 Commitment". Below the header, a large green banner reads "Fill your EFFEXOR XR prescription for \$4." It states that eligible patients will pay a minimum of \$4 and receive savings of up to \$75 per refill. A sample of the \$4 Co-Pay Commitment card is displayed, featuring the text "Fill your EFFEXOR XR prescription for only a \$4 co-pay*", the drug name "VENLAFAXINE HCl", and "EFFEXOR XR". The card also includes a "BIN: 610020", "Group: 99992007", and "ID# XXXXXXXX". A note on the card states: "This card is not health insurance. It cannot be used with Medicare or Medicaid." To the right of the card, there is a link to "Terms and Conditions" and a "Register Now" button. Below the card, it says "Valid from 4/15/2010 to 12/31/2013." Further down, it specifies "No membership fees. This co-pay card is not health insurance. This co-pay card is accepted only at participating pharmacies." A phone number "877-612-1148" is provided for questions.

²⁶ Effexor XR, <http://www.effexorxr.com/default.aspx> (last visited Dec. 6, 2011)

Patients who fill their prescriptions with a mail-order pharmacy receive the following savings under the program:

- For a 90-day supply, the consumer pays the first \$10 and Pfizer pays the remaining amount, up to \$225, or the amount of the consumer's co-pay, for a maximum savings of \$1,000 per calendar year.
- For a 60-day supply, the consumer pays the first \$8 and Pfizer pays the remaining amount, up to \$150, or the amount of the consumer's co-pay, for a maximum savings of \$1,000 per calendar year.

90. The program runs through December 31, 2013.

91. The Effexor XR \$4 Co-pay Commitment Program is not a need-based program.

It is open to all patients with commercial prescription insurance coverage for Effexor XR. A patient can sign up by answering a few short questions and providing his or her name and address on Pfizer's website: <https://www.effexorxr.com/signup.aspx>. Once registered, patients may print a temporary savings card to use immediately. A permanent card is sent by mail within one to two weeks.

c. The Effexor XR \$4 Co-Pay Commitment Program specifically provides that it does not apply to Medicare or Medicaid patients or to residents of Massachusetts.

92. When enrolling in the \$4 Co-Pay Commitment Card program, members are asked whether they purchase prescription medication through Medicare, Medicaid, or a similar federal or state prescription drug program and whether, if they reside in Massachusetts, they have insurance coverage for their prescription medication. If a patient selects, "Yes, I live in Massachusetts and have insurance coverage for my prescription," he/she is told, "We are sorry. You are not eligible for this offer." The same message is displayed if the patient indicates that he/she receives benefits through the federal or state government.

93. The fine print Terms and Conditions printed on Pfizer's patient website similarly state,

The Card is *not* valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare or other federal or state healthcare programs, including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico (formerly known as "La Reforma de Salud").

The Card is not valid for Massachusetts residents whose prescriptions are covered in whole or in part by third-party insurance...

4. Amgen and Pfizer's Enbrel Support Card.

a. Amgen faced competition from less expensive therapeutic alternatives after the launch of Enbrel.

94. On November 2, 1998, the FDA approved Enbrel (etanercept) to treat rheumatoid arthritis. By 2005 and 2006, Enbrel was achieving annual sales for Amgen of over \$1 billion. By mid-2006, however, sales began to decline. Amgen reported to its investors that “Enbrel is a product that isn’t performing up to our expectations.”²⁷ Amgen executives explained that increased co-pays and co-insurance cost-sharing were steering patients away from Enbrel (which had average co-pays of around \$40 to \$50 dollars per prescription), but that Amgen was “dealing with it” by increasing the level of co-pay assistance it provided to patients. When an audience member seemed uneasy about this because “the patients are supposed to be responsible for [the co-pays],” Amgen’s Vice President of Commercial Operations, George Morrow, assured him that the plan had been approved by the company’s legal department and “[b]y the way, the other companies have some co-pay assistance as well, so I think it’s good for all of us to do that and keep the marketplace going.” In short, Amgen’s justification was essentially, “everyone’s doing it.”

95. At this time, Amgen did not have its own co-pay subsidy plan for Enbrel, but donated money to supposedly independent nonprofit foundations that provided co-pay assistance for a number of drugs, including Enbrel. In the words of Amgen’s Vice President of Investor Relations Arvind Sood’s:

And you know that tends to serve as a pretty significant impediment for the patient because all of a sudden, instead of paying whatever \$40 to \$100 in terms of your fixed copayment, especially with a product like Enbrel where the cost of therapy is about \$10,000. And if you’re being told that, look, you have to pay 20% of that, that is a pretty meaningful

²⁷ George Morrow, Amgen EVP of Commercial Operations, *Amgen at Goldman Sachs Annual Global Healthcare Conference – Final*, FD (Fair Disclosure) Wire (June 14, 2006).

deterrent.

Now what we have been doing is we have been working with many of the copay assistance foundations. Now these are nonprofit foundations, so we can't go out and tell them that you need to channel your resources towards Enbrel patients. So we make a contribution to them and they in turn provide assistance to those individuals who are not able to afford their copayments.²⁸

96. By the start of 2009, sales of Amgen reported that "Enbrel was down 5% as growth rates declined sharply for both rheumatology and dermatology segments."²⁹

97. Less expensive therapeutic alternatives to Enbrel include prescription analgesics (acetaminophen and tramadol), prescription NSAIDS (ibuprofen and naproxen), corticosteroids (prednisone) and nonbiologic disease-modifying anti-rheumatic drugs (cyclosporine (Sandimmune, Neoral), azathioprine (Imuran), leflunomide (Arava), methotrexate (Rheumatrex, Trexall), minocycline, sulfasalazine (Azulfidine), and hydroxychloroquine sulfate (Plaquenil)).

b. In the wake of competition from less expensive therapeutic alternatives, Amgen and Pfizer created the Enbrel *Support Card* co-pay subsidy program.

98. In first quarter 2009, Enbrel was facing competition — not only from less expensive therapeutic alternatives, but also from Abbott's Humira and the Humira Protection Program, another co-pay subsidy program. In line with its "everyone's doing it" philosophy, the company, with co-promoter Pfizer, launched its own co-pay subsidy program, the Enbrel *Support Card*, in or around April 2009.³⁰ The Enbrel *Support Card* covers both Enbrel and Enbrel Sureclick.³¹

²⁸ Amgen at Merrill Lynch Global Pharmaceutical, Biotech & Medtech Conference – Final, FD (Fair Disclosure) Wire (Sept. 22, 2006).

²⁹ George Morrow, EVP - Global Commercial Operations, Q1 2009 Amgen Earnings Conference Call – Final, FD (Fair Disclosure) Wire (Apr. 23, 2009).

³⁰ Enbrel Support Card, <http://www.enbrel.com/ENBREL-support-card-program.jspx> (last visited Dec. 6, 2011).

³¹ Enbrel Sureclick is a pre-filled autoinjector for single-use, only. See Enbrel Injection Options and Demos, <http://www.enbrel.com/inject-ENBREL.jspx> (last visited Mar. 6, 2012).

ENBREL Support™ Card

Join more than 125,000 people who have used our card.



The ENBREL Support™ card provides financial support to eligible* commercially insured patients when presented to the pharmacy.

ENBREL is an injectable prescription medication that treats moderately to severely active rheumatoid arthritis, adult chronic moderate to severe plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and moderately to severely active polyarticular juvenile idiopathic arthritis. ENBREL is not for everyone. Serious side effects are possible. Make sure you read and understand the Important Safety Information and Indications for ENBREL.

For all eligible patients*, the *ENBREL Support™* card program may offer:

- I **6 months** at no out-of-pocket cost to you
- I **\$10 or less** out-of-pocket per month thereafter†
- I **Support** for your ENBREL co-pay or co-insurance and prescription deductible

*Read eligibility criteria & program details

Start Saving ➤

99. As the patient website explains, the *Support* card “provides financial support to eligible commercially insured patients when presented to the pharmacy.” The card is good for one year and can be easily renewed online or by calling a toll-free hotline.

100. Through the Enbrel *Support* program, Amgen and Pfizer pay 100% of the patient’s co-pay for six months. After that time, Amgen and Pfizer subsidize the co-pay such that a prescription costs the patient \$10 or less per month thereafter; each time a patient fills his or her Enbrel or Enbrel Sureclick prescription, Amgen and Pfizer pay 50% of the patient’s co-pay, or an amount that results in the patient paying no more than \$10 per month, whichever results in the patient paying less. Amgen and Pfizer will pay up to \$4,000 per patient for every six-month period. For patients whose conditions require them to take twice-weekly doses, Amgen and Pfizer pay an additional \$2,000 per patient for the first three months of therapy.

101. The Enbrel *Support* Card is not a need-based program. It is open to all patients with commercial prescription insurance coverage for Enbrel. A consumer activates the Enbrel

Support card simply by entering his or her name, address, e-mail address, date of birth and doctor's information into a short, online form available at <https://www.enbrel.com/ENBREL-support-card-form.jspx?form=enroll>.

102. The Enbrel Support Card is advertised directly to individuals through full-color advertisements in magazines with nationwide circulation. For example, a two-page color advertisement for Enbrel appeared in the June 15, 2009 issue of *People* magazine, showing a picture of the Enbrel Support Card and advertising “[n]o co-pay for 6 months for eligible patients” and “\$10 or less co-pay per month thereafter.”

103. Similar advertisements appeared in the February 22, 2010 issue of *People* magazine, the September 2011 issue of *Health* magazine and the September 26, 2011 issue of *Sports Illustrated*.

104. The Enbrel Support Card is also advertised to doctors in medical journals. For example, a full-page advertisement for Enbrel appearing in the January 2010 issue of *The Rheumatologist* introduced the Enbrel Support Program and told doctors “[n]ow paying for ENBREL may be easier for your patients. Go to www.enbrelsupport.com.”

c. Amgen and Pfizer's Enbrel *Support* Card specifically provides that it does not apply to Medicare or Medicaid patients, or to residents of Massachusetts.

105. To enroll in the Enbrel *Support* program, individuals must answer the following questions: (1) “Do you have commercial or private insurance?”, (2) “Do you currently reside in the state of Massachusetts?”, and (3) “Are your prescriptions paid for in part or in full under any state or federally funded programs?” Only privately-insured individuals who are not residents of Massachusetts and who do not have a part of their prescriptions paid by a state or federally funded program may continue in the enrollment process. All others are told, “We're sorry. According to the information you provided, you are **NOT** eligible for the Enbrel *Support* card.”

106. Privately-insured individuals can activate their prescription card and download information immediately:

In addition, an *ENBREL Support™* card will be mailed to you at the address provided; you should receive your card within 7-10 business days.

Please write down the following information for future reference.

These are the identification numbers you will need to provide to the pharmacist.

RxBIN: 610524

RxPCN: Loyalty

RxGRP: 50775095

ISSUER: (80840)

ID: 729604055

107. Under “Program Details,” the website reiterates that the program is “[n]ot open to uninsured patients or patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare including Medicare Part D, Medicaid, etc.) or patients who live in Massachusetts (or where prohibited by law).”

d. The Enbrel *Support* Card functions as an unlawful form of secondary health insurance.

108. The fine print on the back of the Enbrel *Support* card tells pharmacists that it “is not an insurance card.” Pharmacists are nevertheless instructed to run the patient’s primary coverage first and then “input card information as secondary coverage.” Despite Amgen and Pfizer’s disclaimer to the contrary, the card functions as a form of secondary insurance.

e. Amgen’s co-say subsidies worked.

109. By all indications, the Enbrel *Support* Card has been a major success. By second quarter 2009, Amgen was already announcing that adoption of the program was “significant.” The company told investors that Enbrel’s market share was holding steady and sales were up despite new generic competition in the rheumatology market:

On a sequential quarterly basis, *Enbrel sales were up 19%*. 14% of this increase was demand-driven, with solid growth in both rheumatology and dermatology segments and stable share versus our competition. During the second quarter, US Enbrel maintained its leadership position in both rheumatology and dermatology. *We saw two new competitors launch in rheumatology recently, yet Enbrel held its share at 34%*. And in

dermatology, Enbrel continues to get the majority of this first-line biologic use for psoriasis, capturing more than 60% of the dollar share in the segment during the quarter. *On our first quarter call, we mentioned the launch of a new co-pay program for commercially insured patients, noted Enbrel Support, and during the second quarter, adoption of this program was significant.* This program, together with our other patient assistance programs, ensures that appropriate patients in need of treatment are able to start and stay in therapy during these tough economic times.³²

110. Throughout 2009 and 2010, Amgen reported that it continued to enhance its co-pay programs, that “early data is encouraging” and that the “programs had solid uptake.”³³

5. Pfizer’s Geodon \$4 Co-Pay Card

a. Pfizer faced competition from less expensive therapeutic alternatives after the launch of Geodon.

111. Pfizer’s atypical antipsychotic Geodon is available in capsule form as ziprasidone hydrochloride. It was approved by the FDA to treat schizophrenia in 2001, and in 2004 the FDA extended its approval to include Geodon as monotherapy in the treatment of acute manic or mixed episodes in bipolar I disorder, with or without psychotic features.

112. In 2008, when Geodon’s sales had reached close to \$800 million, Pfizer CEO Jeff Kindler labeled Geodon (along with Xalatan, Viagra, and Lipitor), as one of four of the companies’ “more mature in-line products” that were “successfully defending their positions against newer agents” in a “tough US marketplace.”³⁴

113. In 2010, Geodon’s sales held strong at \$900 million. Geodon’s patent expired on March 2, 2012, and generic Geodon is now readily available.

114. Less expensive therapeutic alternatives to Geodon include generic Geodon, risperidone (Risperdal), and olanzapine (Zyprexa).

³² George Morrow, EVP - Global Commercial Operations, Amgen, Q2 2009 Amgen Earnings Conference Call – Final, FD (Fair Disclosure) Wire (July 27, 2009) (emphasis added).

³³ Event Brief of Q4 2009 Amgen Earnings Conference Call – Final, FD (Fair Disclosure) Wire (Jan. 25, 2010); Q1 2010 Amgen Earnings Conference Call – Final, FD (Fair Disclosure) Wire (Apr. 21, 2010).

³⁴ Q2 2008 Pfizer Earnings Conference Call – Final, FD (Fair Disclosure) Wire (July 23, 2008).

115. Pfizer actively encourages patients who were prescribed Geodon to continue to use name brand Geodon, despite the generic's entry into the market, and the company provides guidance on its website concerning how to "ensure that the pharmacy doesn't give [the patient] a generic substitute."³⁵

▼ **I prefer brand-name GEODON. How can I ensure that the pharmacy doesn't give me a generic substitute?**

When you receive your prescription, check that the bottle is labeled "GEODON." Tell your pharmacist or doctor that you prefer brand-name GEODON and discuss your options.

b. In the wake of substitution competition from less expensive therapeutic alternatives, Pfizer created the Geodon co-pay subsidy program.

116. In 2011, Pfizer started offering \$4 Co-Pay Cards, which allowed consumers to "[s]ave up to \$900 per calendar year."³⁶



GEODON \$4 Co-Pay Card
Pay as low as \$4 a month for GEODON with the GEODON \$4 Co-Pay Card.
 Save up to \$900 per calendar year.

If your insurance co-pay is:

- \$79 or less, you pay only \$4
- \$80 or more, save \$75 off your monthly cost

Eligibility required. [Terms and conditions](#) apply. **Card will be accepted only at participating pharmacies. Card is not health insurance.** No membership fee. For more information call 1-800-725-9655 or write to Pfizer, PO Box 29387, Mission, KS 66201-9618.

[Get answers](#) to frequently asked questions about the GEODON \$4 Co-Pay Card.

117. The co-pay subsidy program provides that if an individual's private insurance co-pay is "\$79 or less, you pay only \$4," and that if the private insurance co-pay is "\$80 or more, [you] save \$75 off your monthly cost."³⁷

³⁵Geodon \$4 Co-Pay Card Frequently Asked Questions, <https://www.geodon.com/copay-card-faqs.aspx> (last visited Mar. 5, 2012).

³⁶ Geodon \$4 Co-Pay Card, <https://www.geodon.com/copay-card-form.aspx?o=request> (last visited Mar. 5, 2012).

³⁷ Geodon \$4 Co-Pay Card, <https://www.geodon.com/.copay-card-form.aspx?o=request> (last visited Nov. 30, 2011).

118. The Geodon \$4 Co-Pay Card is not a need-based program. It is open to all patients with a prescription for Geodon, and it subsidizes the co-pays of any commercially-insured patients. Starting in 2011, patients could sign up for the Geodon \$4 Co-Pay Card directly on Pfizer's website.

119. Even though generic Geodon has entered the market, Pfizer still actively promotes the co-pay subsidy program for name brand Geodon, and the company encourages patients to use the co-pay subsidy card to save money on brand name Geodon.

120. In fact, Pfizer tells patients that, by using the Geodon \$4 Co-Pay Card, they could actually be paying *less* to continue using name brand Geodon than they would pay for the generic alternative: “[W]ith the GEODON \$4 Co-Pay Card, eligible patients pay as low as \$4 a month for GEODON. That’s less than the average cost of a generic in the same class of medicines.”³⁸

Frequently asked questions [Show all](#) | [Hide all](#)

Click on a question for the answer.

See [terms and conditions](#). Card will be accepted only at participating pharmacies. Card is not health insurance. No membership fee. For more information call 1-800-725-9655 or write to Pfizer, PO Box 29387, Mission, KS 66201-9618.

▼ My doctor told me that GEODON has gone generic. Can I still get brand-name GEODON?

Yes. Although a generic form of GEODON is now available, you can continue your treatment with brand-name GEODON. And with the GEODON \$4 Co-Pay Card, eligible patients pay as low as \$4 a month for GEODON. That’s less than the average cost of a generic in the same class of medicines. [Terms and Conditions apply](#)

▼ What does it mean that GEODON has “gone generic?”

Previously, only Pfizer could manufacture GEODON. Now other companies can manufacture a generic version of GEODON using the same main ingredient.

Although a generic form of GEODON is now available, you can continue your treatment with brand-name GEODON. And with the GEODON \$4 Co-Pay Card, eligible patients pay as low as \$4 a month for GEODON. That’s less than the average cost of a generic in the same class of medicines. [Terms and Conditions apply](#)

▼ Can the GEODON \$4 Co-Pay Card be used with the generic form of GEODON?

No. The Card can only be used toward the co-pay for brand-name GEODON.

³⁸ Geodon \$4 Co-Pay Card Frequently Asked Questions, <https://www.geodon.com/copay-card-faqs.aspx> (last visited Mar. 5, 2012).

c. **Pfizer's Geodon \$4 Co-Pay Card specifically provides that it does not apply to Medicare or Medicaid patients, or to residents of Massachusetts.**

121. Pfizer's website provides that the \$4 co-pay card offer is:

not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare, or other federal or state health care programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico formerly known as 'La Reforma de Salud'). . . . Card is not valid for Massachusetts residents whose prescriptions are covered in whole or in part by third-party insurance, or where otherwise prohibited by law.

d. **The Geodon co pay subsidy card functions as an unlawful form of secondary health insurance.**

122. The fine print on Pfizer's website states that the Geodon \$4 Co-Pay Card "is not health insurance." However, the \$4 Co-Pay Card instructs the pharmacist:

TO PHARMACIST:

- For insured patients, process a coordination of benefits (COB/split bill) claim using the patient's prescription insurance for PRIMARY claim. Submit SECONDARY claim to PDM under BIN # 610020.

Despite Pfizer's disclaimer, the coupon functions as a form of secondary insurance.

e. **Pfizer knows that third party payors cannot tell when a co-pay is subsidized.**

123. Pfizer knows that the Geodon co-pay subsidy program that it and its co-pay card administrator have designed makes it impossible for third party payors to tell if their members' co-pays are being subsidized by co-pay savings cards. Pfizer admits as much in the fine print of the Geodon \$4 Co-Pay Card's Terms and Conditions, where it attempts to push onto patients the responsibility for making such disclosures: "You must deduct the value of the Card from any reimbursement request submitted to your insurance plan, either directly by you or on your behalf." By burying this disclosure in the fine print of the card's Terms and Conditions,

however, Pfizer makes a weak attempt to shield itself from liability with instructions it knows and intends will not be seen or followed.

Terms and Conditions

close X

By using the GEODON \$4 Co-Pay Card, you acknowledge that you currently meet the eligibility criteria and will comply with the following terms and conditions. Offer is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare, or other federal or state health care programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico formerly known as "La Reforma de Salud"). Offer is not valid for prescriptions that are eligible to be reimbursed by private insurance plans or other health or pharmacy benefit programs that reimburse you for the entire cost of your prescription drugs. By using the Card, patients will receive savings of up to \$75 per fill and pay a minimum of \$4 per fill. The Card is good for a maximum of \$900 per year. After a maximum of \$900, patient will pay monthly out-of-pocket costs. The Card may be used once per month for the life of the program.

You must deduct the value of the Card from any reimbursement request submitted to your insurance plan, either directly by you or on your behalf. Card is not valid for Massachusetts residents whose prescriptions are covered in whole or in part by third-party insurance, or where otherwise prohibited by law. Card cannot be combined with any other rebate/coupon, free trial, or similar offer for the specified prescription. **Card will be accepted only at participating pharmacies. Card is not health insurance.** Offer good only in the US and Puerto Rico. Card is limited to 1 per person during this offering period and is not transferable. Pfizer reserves the right to rescind, revoke, or amend this offer without notice. No membership fee. Offer expires 12/31/2012.

For further information call 1-800-725-9655.

Pfizer, PO Box 29387, Mission, KS 66201-9618

6. Pfizer's Lipitor Co-Pay Cards

a. Pfizer faced competition from less expensive therapeutic alternatives after the launch of Lipitor.

124. On December 17, 1996, FDA approved Warner-Lambert's statin Lipitor (atorvastatin calcium) to treat hypercholesterolemia and mixed dyslipidemia. Even before FDA approval, Warner-Lambert knew that it could not market Lipitor on its own; a 1995 sales force deployment study had revealed that the Warner-Lambert's sales force was too small to effectively launch Lipitor. Warner-Lambert chose Pfizer to help market Lipitor. Pfizer later acquired Warner-Lambert in 2000.

125. Warner-Lambert and Pfizer assembled the largest statin sales force ever. Between Warner-Lambert and Pfizer, more than 2,200 sales representatives were selling Lipitor when it launched in January 1997.

126. Lipitor reached \$1 billion in U.S. sales within its first twelve months on the market. By October 1997, Lipitor had claimed a 30% share of all new statin prescriptions in the U.S. market. By 2006, Lipitor accounted for 43% of all U.S. statin prescriptions, and domestic sales topped \$8.6 billion.

127. As early as 2006, Pfizer faced competition from non-AB rated generic statins and therapeutic alternatives. Less expensive therapeutic alternatives to Lipitor include pravastatin (Pravachol) and simvastatin (Zocor). Generic pravastatin entered the market in April 2006; generic simvastatin came to market in June 2006. Given the high cost of branded maintenance cholesterol-reducing drugs, cost-sharing mechanisms in prescription drug plans incentivized substitution within the therapeutic class of statins.

128. In 2006, substitution competition in the statin therapeutic class quickly materialized: Pfizer's Lipitor share of new statin prescriptions immediately began to fall. From 2006 through 2010, increased competition from less expensive statins caused overall U.S. sales of Lipitor to drop by over \$1.4 billion annually, from a high of about \$8.6 billion in 2006 to about \$7.2 billion in 2010.

129. To fight the erosion of Lipitor's market share, Pfizer implemented its unlawful scheme to undermine cost sharing in private health benefit plans. According to Pfizer, “[i]nitially, we [offered Lipitor co-pay subsidies] quite honestly because we were facing a generic presence in the marketplace. We also did it because prescribing decisions were being based not just on clinical factors, but also cost.”³⁹

³⁹ Shirley S. Wang, *Drug Makers Circumvent Co-Pays Using Rebates*, Wall Street Journal Health Blog (July 20, 2009), available at <http://blogs.wsj.com/health/2009/07/20/drug-makers-circumvent-co-pays-using-rebates/>.

130. Pfizer's actions prevented patients from purchasing less-expensive generic Lipitor equivalents for at least twenty months, as it was not until November 30, 2011, that a generic bioequivalent was made available to consumers.

b. In the wake of substitution competition from less expensive therapeutic alternatives, Pfizer created its first Lipitor co-pay subsidy program.

131. In or around late 2006 or early 2007, Pfizer began offering a Lipitor co-pay card ("original Lipitor co-pay card" or "Lipitor \$120/\$180 co-pay card") that provided smaller co-pay subsidies than would eventually be offered under a subsidy program instituted in 2010, the "Lipitor \$4 Co-Pay Card." The original Lipitor co-pay card saved individuals up to \$180 a year. If a privately-insured individual's co-pay was less than \$35, he or she saved either \$10 or the amount of his co-pay (whichever was less) every month. If a privately-insured individual's co-pay was \$35 or greater, he or she saved \$15 per co-pay. According to Pfizer's website for doctors,

When your eligible patient's insurance co-pay is:

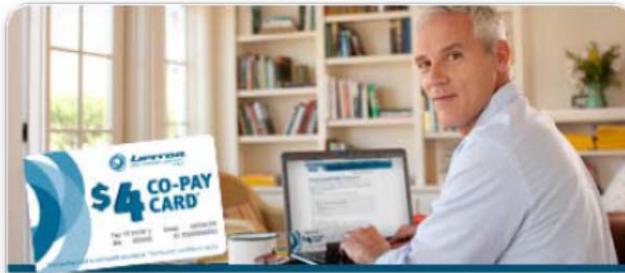
Less than \$35, your patient will instantly receive \$10 or the amount of their co-pay (whichever is less), up to 12 times per year, for \$120 in savings

\$35 or more, your patient will instantly receive \$15 toward their co-pay, up to 12 times per year, for \$180 in savings

c. Approximately one year before an AB-rated Lipitor generic came to market, Pfizer increased its co-pay subsidies to \$50 per prescription (or \$600 per individual per year).

132. In or around December 2010, Pfizer began offering the Lipitor \$4 Co-Pay Card to privately-insured members taking statins.⁴⁰

⁴⁰ Lipitor for You, <https://www.lipitor.com/patients/LIPITORforYou.aspx#> (last visited Mar. 5, 2011).



LIPITOR \$4 Co-Pay Card

Eligible patients can get LIPITOR for as low as a \$4 co-pay per month. With the LIPITOR \$4 Co-Pay Card you can save at your local participating pharmacy or choose to sign up for direct delivery of LIPITOR.

[LIPITOR \\$4 Co-Pay Card terms and conditions apply.](#)

Get Started

Select one of the following:

I would like to sign up for a LIPITOR \$4 Co-Pay Card.

If you do not yet have a LIPITOR \$4 Co-Pay Card, select this option to register for one.

Next >

I already have a LIPITOR Co-Pay Card.

If you have already received a LIPITOR Co-Pay Card, select this option and enter your card number below.

Next >

Co-Pay Card **Direct Delivery** **Tips & Tools**

133. Pfizer pays up to \$50 towards each Lipitor co-pay, up to a maximum of \$600 per member per year. As Pfizer's Lipitor website states, “[i]f your insurance co-pay is: \$54 or less, you pay only \$4. \$55 or more, save \$50 off your monthly cost, up to \$600 of savings per calendar year.”⁴¹ The terms and conditions of the Lipitor \$4 Co-Pay Card program confirm these terms:

If your out-of-pocket expenses for a 1-month supply (30 tablets) are \$54 or less, you will pay \$4 for a 1-month supply. If your out-of-pocket expenses for a 1-month supply (30 tablets) exceed \$54, you qualify for up to \$50 in savings for a 1-month supply. In either case, you can only qualify for up to \$600 of savings per calendar year. After [a] maximum of \$600, you will pay usual monthly out-of-pocket costs.⁴²

134. The Lipitor \$4 Co-Pay Card is not a need based program; privately-insured members can participate regardless of their income or financial need, as long as their cost-share expense is more than \$4 per prescription.

⁴¹ See Lipitor Co-Pay Card patient website, available at <https://www.lipitor.com/patients/lipitorcopaycard.aspx> (last visited August 2011).

⁴² Lipitor for You, <https://www.lipitor.com/patients/LIPITORforYou.aspx#> (last visited March 5, 2011).

135. Individuals are warned that the offer is good only at participating pharmacies. However, if a patient's pharmacy does not participate in the Lipitor co-pay card program, Pfizer will reimburse the patient's co-pay by mail:

For reimbursement when using a non-participating pharmacy/mail order: Pay for LIPITOR prescription and mail copy of original pharmacy receipt (cash register receipt NOT valid) with product name, date and amount circled to:

LIPITOR Co-Pay Card
6501 Weston Parkway, Suite 370
Cary, NC 27513

Be sure to include a copy of the front of your Co-Pay Card, your name and mailing address.

136. Privately-insured individuals enroll in the program by entering their name, address, and date of birth into a form on Pfizer's website:

<https://www.lipitor.com/patients/lipitorcopaycard.aspx>. Individuals receive a card in the mail about four weeks after enrolling in the program.

137. The Lipitor \$4 Co-Pay Card purportedly expires on December 31, 2012, although Pfizer still allows individuals to use an earlier iteration of a co-pay card that nominally expired in December 2009.

138. The Lipitor \$4 Co-Pay Card is advertised directly to individuals on television and radio. For example, a radio advertisement in the Chicago area on WGN-FM 101.1 at approximately 7:30 a.m. on December 8, 2011 told individuals how to obtain the card. Listeners were also told to "see [Pfizer's] ad in *Cooking Light* magazine." An ad for Lipitor that aired on CBS on September 26, 2011 concluded by saying, "Lipitor may be available for as little as \$4 a month with a Lipitor Copay card. Terms and conditions apply. Learn more at lipitortoryou.com."

139. The Lipitor \$4 Co-Pay Card is also advertised through full-color advertisements in magazines and newspapers. For example, the October 3-9, 2011 issue of *Bloomberg Business Week* included an advertisement featuring the Lipitor \$4 Co-Pay Card. It told readers to “Stay with Lipitor for as little as \$4 a month. Get the \$4 Co-Pay Card with the new Lipitor For You program.” Similar advertisements appeared in the October 3, 2011 issue of *Sports Illustrated* and the October 5, 2011 issue of The Baltimore Sun.

140. Pfizer’s Lipitor \$4 Co-Pay Card was seen as an “aggressive marketing move” by its competitors. As indicated in comments posted to online discussion boards by sales representatives for AstraZeneca, whose drug Crestor was also battling generic competition in the statin therapeutic class, the co-pay card was expected to allow Pfizer to “clean house” in the statin market:

Yes, this is true! Starting next week the Pfizer reps will be delivering \$4.00 co-pay cards to offices. I have heard our upper management does know about this information. This is quite the aggressive marketing move by Pfizer. They will take over the statin market! They will get all new starts, they will get all of Crestor new and existing starts and clean house.⁴³

This is Pfizer’s way of taking on the generics. . . . This is a great way for Pfizer to blunt the 1st generic on the market.⁴⁴

Commercial insurance will be totally Lipitor. . . . It will dominate the generics and will be demanded by patients.⁴⁵

A desperate attempt by Pfizer to slow the generic erosion. They actually have a better chance than us in the new world turned upside down of statins. . . .⁴⁶

⁴³ Anonymous post to AstraZeneca discussion board at cafepharma.com on Dec. 17, 2010.

⁴⁴ Anonymous post to AstraZeneca discussion board at cafepharma.com on Dec. 22, 2010.

⁴⁵ Anonymous post to AstraZeneca discussion board at cafepharma.com on Dec. 27, 2010.

⁴⁶ Anonymous post to AstraZeneca discussion board at cafepharma.com on Dec. 4, 2010.

Smart move on Pfizer's part. They should have 95% market share within a few months.⁴⁷

141. Pfizer's own sales representatives realized that, with a marketing ploy like this, Lipitor would essentially "sell itself":

They are charging the same old price. The customer gets a coupon that reduces the cost of out of pocket expense to \$4. Health plans pay the same amount to Pfizer. . . . Pfizer still makes plenty. . . .⁴⁸

It's meant to deter patients from switching to a generic statin based solely on price.⁴⁹

\$4 Lipitor will take the vast majority of the market and keep it! They won't need us to promote it anymore because it will promote itself!⁵⁰

d. Pfizer's Lipitor co-pay subsidy programs specifically provide that they do not apply to Medicare or Medicaid patients, or to residents of Massachusetts.

142. When enrolling in the \$4 Lipitor Co-Pay Card program (and presumably upon enrolling in the original Lipitor co-pay card program) members are asked whether they purchase prescription medication through Medicare, Medicaid, or a similar federal or state prescription drug program and whether, if they reside in Massachusetts, they have insurance coverage for their prescription medication. If a patient selects, "Yes, I live in Massachusetts and have insurance coverage for my prescription," they are told, "We are sorry. You are not eligible for this offer." The same message is displayed if the patient indicates that they receive benefits through the federal or state government.

⁴⁷ Anonymous post to AstraZeneca discussion board at cafepharma.com on Dec. 4, 2010.

⁴⁸ Anonymous post to Pfizer discussion board at cafepharma.com on Dec. 21, 2010.

⁴⁹ Anonymous post to Pfizer discussion board at cafepharma.com on Dec. 21, 2010.

⁵⁰ Anonymous post to Pfizer discussion board at cafepharma.com on Dec. 22, 2010.

143. The fine print “terms and conditions” printed on Pfizer’s patient website similarly state:

This Card is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare or other federal or state healthcare programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico [formerly known as “La Reforma de Salud”])

The Card is not valid for Massachusetts’s residents whose prescriptions are covered in whole or in part by third-party insurance. . . .

7. Pfizer’s Pristiq Savings Card

a. **Pfizer faced competition from less expensive therapeutic alternatives immediately after Pristiq’s launch.**

144. On February 29, 2008, the FDA approved Pristiq, Wyeth Pharmaceutical’s serotonin-norepinephrine reuptake inhibitor (SNRI), to treat major depressive disorder (MDD).

145. Pristiq was designed to be the antidepressant successor to Wyeth’s Effexor and Effexor XR, as Effexor XR was set to lose patent protection in 2010 and had \$3.8 billion a year in sales. In fact, the active ingredient in Pristiq is a metabolite of Effexor and Effexor XR.

146. Pristiq was called a “blatant patent extender” by blogger and psychiatrist Daniel Carlat, M.D.

Effexor XR, which brought in \$3.8 billion for Wyeth in 2007, is losing patent protection this year, and Wyeth is introducing desvenlafaxine, which is simply Effexor’s main metabolite, as a “novel antidepressant.” There’s nothing novel about it. Every patient who takes Effexor produces Pristiq in their own body, at no additional charge.⁵¹

147. Despite its critics, Wyeth expected sales of Pristiq to be close to \$2 billion per year.

⁵¹ See Daniel Carlat, M.D., Top 5 Reasons to Forget about Pristiq, *The Carlat Psychiatry Blog* (Mar. 1, 2008), <http://carlatpsychiatry.blogspot.com/2008/03/top-5-reasons-to-forget-about-pristiq.html>.

148. Wyeth's first-half sales numbers for Pristiq in 2009 were lower than expected, and were even omitted from earnings reports. At the end of 2009, Wyeth reported only \$267 million in sales for Pristiq.

149. Effective October 15, 2009, Pfizer acquired Wyeth in a cash and stock merger.

150. Pristiq's sales continued to suffer when Venlafaxine, a generic version of Effexor, came to market in 2010.

151. Less expensive therapeutic alternatives to Pristiq include selective serotonin reuptake inhibitors (SSRIs) – such as sertraline (Zoloft), citalopram (Celexa), bupropion XL (Wellbutrin XL), fluoxetine (Prozac) – and selective serotonin norepinephrine reuptake inhibitors (SNRIs) – such as instant release venlafaxine (Effexor).

b. In the wake of substitution competition from less expensive therapeutic alternatives, Pfizer created the Pristiq Savings Card.

152. Prior to 2010, patients could become eligible for a savings card through their doctors (the "Start Today" program). This card provided a discount of 50% off of the prescription co-pay or out-of-pocket costs for the duration of the patient's treatment.

153. The Start Today program is no longer used by Pfizer; however, in 2011, Pfizer started offering Pristiq Savings Cards that allow patients to save up to \$180 per year:⁵²

⁵² Savings Card Eligibility, https://www.pristiq.com/pristiq_savings_card_eligibility.aspx (last visited Dec. 6, 2011).

If you are eligible, you can save up to \$15 a month — up to \$180 per year on your out-of-pocket cost— by using the PRISTIQ Savings Card at your pharmacy.

You can download your temporary card right here and we'll mail you your permanent card within 7-14 days.

You'll see up to \$15 deducted from your out-of-pocket cost on every prescription. This discount is available to patients 18 or older **with or without prescription drug coverage**. Not valid for residents of Massachusetts. See other [Eligibility/Terms & Conditions below.*](#)



154. According to the Pristiq Savings Card website, patients who use Pristiq “will save either \$15 or the amount of [their] co-pay/out-of-pocket cost, whichever is less.”

155. The Pristiq Savings Card is not a need-based program; privately-insured members can participate regardless of their income or financial need.

156. Privately-insured individuals enroll in the program by entering their name, address, and date of birth into a form on Pfizer’s website:

https://www.pristiq.com/pristiq_savings_card_eligibility.aspx. Individuals can immediately download a temporary card and receive a permanent card within seven to fourteen days.

157. The Pristiq Savings Card program purportedly expires on December 31, 2012.

c. **Pfizer’s Pristiq Savings Card specifically provides that it does not apply to Medicare or Medicaid patients, or to residents of Massachusetts.**

158. When enrolling in the Pristiq Savings Card program, members are asked whether they purchase prescription medication through Medicare, Medicaid, or a similar federal or state prescription drug program and whether, if they reside in Massachusetts, they have insurance coverage for their prescription medication. If a patient selects, “Yes, I live in Massachusetts and have insurance coverage for my prescription,” he or she is told, “We are sorry. You are not

eligible for this offer.” The same message is displayed if the patient indicates that he or she receives benefits through the federal or state government.

159. The fine print “terms and conditions” printed on Pfizer’s patient website similarly state:

This Card is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare or other federal or state healthcare programs including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico (formerly known as “La Reforma de Salud”).

* * *

The Card is not valid for Massachusetts’s residents whose prescriptions are covered in whole or in part by third-party insurance...

d. The Pristiq Savings Card functions as an unlawful form of secondary insurance.

160. The fine print on Pfizer’s website states that the Pristiq Savings Card “is not health insurance.” However, the card has clear instructions to pharmacists to “process a coordination of benefits (COB/split bill) claim using patient’s prescription insurance for the PRIMARY claim. Submit secondary claim to PDM under the BIN #610020.” Despite Pfizer’s disclaimer, the coupon functions as a form of secondary insurance.

e. Pfizer knows that third party payors cannot tell when a co-pay is subsidized.

161. Pfizer knows that the Pristiq co-pay subsidy program that it and its co-pay card administrator have designed makes it impossible for third party payors to tell if their members’ co-pays are being subsidized by co-pay savings cards. Pfizer admits as much in the fine print of the Pristiq Savings Card’s Terms and Conditions, where it attempts to push onto patients the responsibility for making such disclosures: “You must deduct the value received under this

program from any reimbursement request submitted to your insurance plan, either directly by you or on your behalf.” By burying the disclosure in the fine print of the card’s Terms and Conditions, Pfizer makes a weak attempt to shield itself from liability with instructions it knows and intends will not be seen or followed.

By using the PRISTIQ Savings Card, you acknowledge that you currently meet the eligibility criteria and will comply with the terms and conditions described below:

Terms & Conditions:

- The Card is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare, or other federal or state health care programs including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico (formerly known as "La Reforma de Salud").
- The Card is not valid for prescriptions that are eligible to be reimbursed by private insurance plans or other health or pharmacy benefit programs which reimburse you for the entire cost of your prescription drugs.
- You will save either \$15 or the amount of your co-pay/out-of-pocket cost, whichever is less. Card can only be used for up to 12 prescriptions a year.
- You must deduct the value received under this program from any reimbursement request submitted to your insurance plan, either directly by you or on your behalf.
- The Card is not valid for Massachusetts residents whose prescriptions are covered in whole or in part by third-party insurance, or where otherwise prohibited by law.
- Cannot be combined with any other rebate/coupon, free trial, or similar offer for the specified prescription.
- **The Card will be accepted only at participating pharmacies.**
- **This Card is not health insurance.**
- Offer good only in the U.S. and Puerto Rico.
- The Card is limited to one person during this offering period and is not transferable.
- Pfizer reserves the right to rescind, revoke, or amend the program without notice.
- No membership fees.
- Card and program expire 12/31/2012.

8. Amgen’s Sensipar Pharmacy Card

a. Amgen faced competition from less expensive therapeutic alternatives to Sensipar.

162. On March 8, 2004, the FDA approved Sensipar (cinacalcet hydrochloride) to treat patients on dialysis who produce too much parathyroid hormone, a condition known as secondary hyperparathyroidism (HPT), and patients with hypercalcemia caused by parathyroid carcinoma.

163. By the end of 2008, sales of Sensipar had grown to nearly \$350 million per year.

In early 2009, Amgen predicted that the drug could be its next “blockbuster product.”⁵³

164. By spring of 2009, George Morrow, Amgen’s Executive Vice President of Global Commercial Operations, noted that some third party payors were restricting access to Sensipar.⁵⁴

165. Amgen’s CEO, Kevin Sharer, however, assured investors that Amgen was equipped to handle such situations: “we are differently this year implementing some dramatically I think helpful and appropriate programs to help patients who have perhaps trouble on co-pays and kind of economic barriers that are more and more set in place.”⁵⁵

166. Less expensive therapeutic alternatives to Sensipar include calcitrol, doxercalciferol (Hectorol), and paracalcetol (Zemplar).

b. In the wake of substitution competition from less expensive therapeutic alternatives, Amgen created the Sensipar Pharmacy Card.

167. To combat the substitution competition it was facing from less expensive therapeutic alternatives, in or around 2010, Amgen created the Sensipar Pharmacy Card:⁵⁶

⁵³ Jim Daly, Senior Vice President, North American Operations, Amgen, Amgen at Cowen and Company Healthcare Conference – Final, FD (Fair Disclosure) Wire (Mar. 18, 2009).

⁵⁴ Q1 2009 Amgen Earnings Conference Call – Final, FD (Fair Disclosure) Wire (Apr. 23, 2009).

⁵⁵ Amgen at Deutsche Bank Healthcare Conference – Final, FD (Fair Disclosure) Wire (May 18, 2009).

⁵⁶ Sensipar Patient Services, Co-Pay Support, <http://www.sensipar.com/patient/sensipar-patient-services/co-pay-support.html> (last visited Mar. 5, 2012); see also sensiparpharmacycard.com.

For People With Commercial Prescription Insurance

Save on Prescription Costs With The Sensipar® Pharmacy Card

Eligible patients can reduce out-of-pocket costs for their Sensipar® prescriptions if they enroll in the Sensipar® Pharmacy Card Program. By using the card, out-of-pocket Sensipar® costs can be as low as only \$5.00.

Most patients who have commercial prescription insurance are eligible to participate in the program. The patient is responsible for the first \$5.00 of out-of-pocket costs. Then, the Sensipar® Pharmacy Card will pay up to \$500 per month (up to \$3,000 every 6 months) to cover out-of-pocket costs for Sensipar®. The Sensipar® Pharmacy Card covers copayments, co-insurance and prescription deductibles.

Enrollment Is Easy

To enroll, please call the Sensipar® Pharmacy Card Program hotline at 1-866-711-4162 or visit www.SensiparPharmacyCard.com.



Learn more about secondary HPT

Sign up for more information.

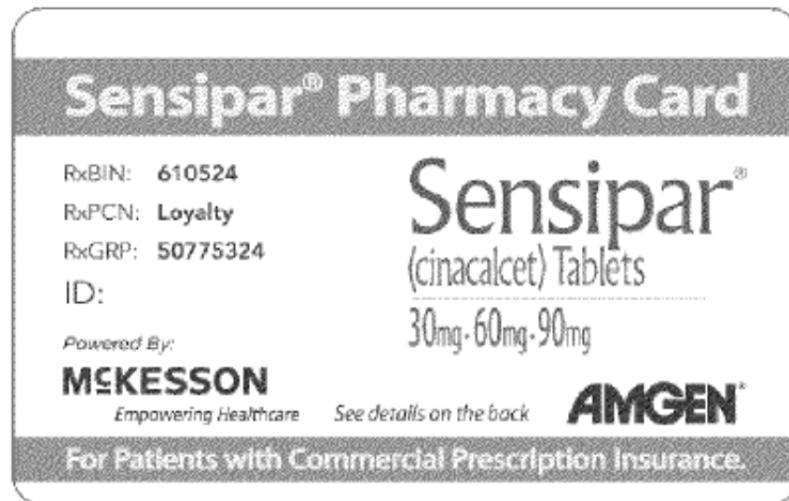
[sign up](#)

168. With the card, a patient is responsible for only the first \$5 of his or her prescription cost. Amgen pays the rest, up to a whopping \$500 for each thirty-day supply (not to exceed a maximum of \$3,000 per six-month period or \$6,000 per year), to cover co-payments, co-insurance, and prescription deductibles.

169. The Sensipar Pharmacy Card is not a need-based program. It is open to all patients with a prescription for Sensipar, and it subsidizes the co-pays of any commercially-insured patients. A patient can sign up for the program and print the card online by providing his or her name, address, e-mail address, date of birth, and the answers to a few short questions on Amgen's website:

<https://www.activatethecard.com/sensipar5324/appSecSensiparValidateResp.jsp>.

170. The patient can print and use a temporary card immediately:



171. A permanent card follows by mail four to six weeks after the temporary card is first used.

c. **The Sensipar Pharmacy Card specifically provides that it does not apply to Medicare or Medicaid patients or to residents of Massachusetts.**

172. Amgen's website and the fine print on the back of the Sensipar Pharmacy Card state the only eligibility requirements, which specifically exclude Medicare or Medicaid patients and residents of Massachusetts:

Please Note:

This program is not open to uninsured patients or patients receiving prescription reimbursement under any federal, state or government-funded insurance programs (for example, Medicare, including Medicare Part D, Medicaid, etc.) or patients who live in Massachusetts (or where prohibited by law).

173. To enroll, patients must verify their state of residence. If they select "Massachusetts," they are told: "You are not eligible to participate in this program because the offer is void in Massachusetts."

174. Finally, to qualify for the program, patients must acknowledge their agreement with the following statement:

Your card is not valid for prescriptions purchased under Medicaid, Medicare or similar federal, state or other government funded insurance programs. Should you begin receiving prescription benefits from such a federal, state or [sic] government funded program at any time, you will no longer be eligible to participate in this program. We may contact you by [sic] phone or mail periodically in order to verify that your eligibility for the program has not changed. Do you acknowledge your agreement with this statement?

175. The reason for this is clear: subsidizing the co-pays of Medicare and Medicaid patients is prohibited as an illegal kickback under federal law. As Jim Daly, Senior Vice President of Amgen, explained to investors wondering why Amgen did not also subsidize the co-pays of Medicare Part D patients: “For Medicare patients, we cannot offset their copay through any mechanism other than donations to a third party independent foundation.”⁵⁷

d. The Sensipar Pharmacy Card functions as an unlawful form of secondary health insurance.

176. The fine print on the back of the Sensipar Pharmacy Card instructs pharmacists to process the card as “secondary coverage” under the coordination of benefits (COB) segment of the National Council of Prescription Drug Programs (“NCPDP”) pharmacy adjudication process:

Pharmacist:

- Submit transaction to McKesson Corporation using Bin #610524
- If primary coverage exists, input card information as secondary coverage and transmit using the COB segment of the NCPDP transaction. Applicable discounts will be displayed in the transaction response.

The card clearly functions as a form of secondary health insurance.

⁵⁷ Q3 2010 Amgen Earnings Conference Call – Final, FD (Fair Disclosure) Wire (Oct. 25, 2010).

G. Defendants hired McKesson, TrialCard, and PDMI to administer their co-pay subsidy programs.

177. Defendants depend on cooperation from both pharmacies and program administrators to conduct these co-pay subsidy programs. Defendants compensate both pharmacies and the co-pay benefit administrators for their efforts. Defendants and co-conspirator administrators process co-pay subsidy claims through a “shadow claims system” that hides the subsidies from health benefit providers.

178. For prescription drugs, plan members present their co-pay cards or coupons along with their health insurance cards (which include the prescription drug plan) at the pharmacy. An individual’s primary insurance is processed first, establishing the individual’s co-pay or co-insurance amount⁵⁸ and the price of the drug that will be billed to the health benefit provider.

179. The pharmacist then processes the co-pay card or coupon associated with the co-pay subsidy program. The pharmacist enters into the pharmacy computer information on the co-pay card as though it were a form of secondary insurance. The pharmacist notes the amount of the co-pay that will be subsidized by the defendants and conveys that information to a co-pay card program administrator who reimburses the pharmacy on the defendants’ behalf.⁵⁹ The plan member pays out-of-pocket the difference between his or her co-payment (or co-insurance) and the amount subsidized by the defendants. The pharmacist then charges the health benefit provider the full amount of the health benefit provider’s usual payment for branded drug in question, *i.e.*, the health benefit provider pays an amount for the co-pay subsidy drug’s purchase as if the plan’s member had made full personal payment of his or her cost-sharing obligation.

⁵⁸ For plan members with a co-insurance responsibility, pharmacists determine the dollar amount to be paid by the member. Sometimes, this amount is referred to, inaccurately, as a “co-pay.”

⁵⁹ The administrator pays pharmacies for all co-pay subsidies on the manufacturer’s behalf every fourteen to twenty-eight days. The manufacturer repays the administrator on a similar schedule.

180. During a transaction *without* the use of the unlawful co-pay subsidy, the pharmacy reports data to the health benefit provider (or its PBM) that enables the provider to know the claim, drug dispensed, amount paid by the plan, amount of co-payment/co-insurance paid, and other data. In a transaction *with* the use of the subsidy, *the information transmitted to the health benefit provider does not include any disclosure that a subsidy was paid*; the plan member's cost-sharing obligation is simply reported to the benefit provider as having been paid.

181. As F. Everett Neville, chief trade relations officer at Express Scripts, one of the country's largest PBMs told the New York Times in January 2011: “[t]he payer doesn't know, and the P.B.M. doesn't know. . . . We have no ability to stop it and no ability to prohibit it.”

182. Here, defendants hired unnamed co-conspirators McKesson, TrialCard, and PDMI (collectively, the “administrators” and the “unnamed co-conspirators”) to administer their co-pay subsidy programs.

1. McKesson administers the Enbrel and Sensipar co-pay subsidy programs for Amgen and Pfizer.

183. On information and belief, McKesson administers the Enbrel and Sensipar co-pay subsidy programs. McKesson is *not* named as a defendant in this action but is an unnamed co-conspirator for purposes of RICO and antitrust violations.

184. McKesson's co-pay subsidy administration program, called LoyaltyScript, “serve[s] more than 17,000 patients every day” and has “saved patients more than \$335 million in out-of-pocket prescription costs.”⁶⁰ According to McKesson, the LoyaltyScript program allows manufacturers to “[i]ncrease market share through co-pay discounts that capture new

⁶⁰ McKesson LoyaltyScript Difference, http://sites.mckesson.com/mprs/solutions/loyaltyscript_difference.shtml (last visited Mar. 6, 2012).

customers" and "[g]ain valuable insight into program utilization to maximize your marketing ROI."⁶¹

185. McKesson holds a patent, applied for on March 31, 2006, for a means of processing co-pay subsidies at the point of sale that is, when the patient brings his prescription to the pharmacy.⁶² McKesson patent contemplates electronically receiving claims from pharmacies that are separate and distinct from claims that are submitted to members' health benefit plans:

What is claimed is: 1. An apparatus comprising: one or more processors configured to receive *an electronic claim transaction* submission at an administrator in response to a purchase transaction of a client at a point of sale of a healthcare provider, *a primary payer separate and distinct from the administrator* also receiving the electronic claim transaction submission from the healthcare provider to initiate adjudication of a primary claim for *an offset of at least a portion of a cost associated with the purchase transaction*, wherein the one or more processors are configured to *adjudicate*, in response to receiving the electronic claim transaction submission and *separate and distinct from the primary claim, one or more services of a program of an administrator to which the client is enrolled*, the purchase transaction being applicable to the program, the one or more services including one or more marketing services or interventions, wherein the one or more processors are also configured to trigger provision of the one or more services to the client in response to adjudication of the one or more services.⁶³

186. McKesson's patent asserts that the pharmaceutical industry had not previously identified a method of providing cost-saving benefits in light of the variability of co-pays:

[previously,] monetary incentives for prescription fulfillment have been limited to a uniform value for a particular product offer. *For insured patients, pharmaceutical marketers have sought the ability to vary the incentives based upon the individual patient's co-pay amount*, which can vary considerably across prescription benefit

⁶¹ McKesson LoyaltyScript Benefits, http://sites.mckesson.com/mprs/solutions/loyaltsript_benefits.shtml (last visited Mar. 6, 2012).

⁶² U.S. Patent No. 7,957,983 (issued June 7, 2011).

⁶³ *Id.* at Claim 1 (emphasis added).

plans based upon individual patient coverage, cost sharing tiers, drug formulary design, and plan exclusions. To date, *no solutions have been identified to address this variability in patient cost-share amounts on a patient-specific basis in real time using the mail-in rebate, debit card or credit card mechanisms.*⁶⁴

187. The patent goes on to state that McKesson's invention solved the industry's "problem" of not being able to undermine health benefit provider's cost-sharing provisions:

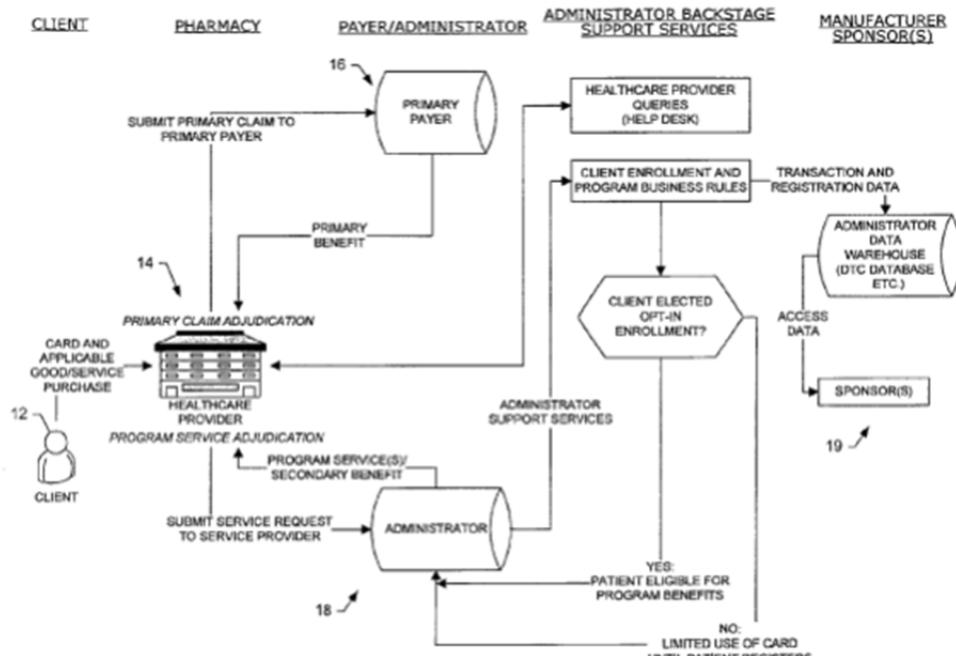
[T]he [monetary] secondary benefit may offset at least a portion of the out-of-pocket expense for a purchase transaction applicable to the respective program. . . . [T]he secondary benefit may be provided in real time at the point of sale . . . by linking secondary benefit with the dispensing and purchase of a medication. The secondary benefit may also be tied to a patient's actual primary benefit, such as by determining the secondary benefit as a percentage of a primary benefit (further offsetting the cost associated with a purchase transaction).⁶⁵

188. McKesson's patent notes that "the adjudications *may* occur sequentially, such that adjudication at the primary payer occurs prior to adjudication at the administrator,"⁶⁶ implying that the adjudications *could instead* take place simultaneously or in the opposite order. Yet Figure 4 (reproduced below) shows two separate feedback loops, one in which the "healthcare provider" (*i.e.* the pharmacy) submits the "primary claim adjudication" to the "primary payer" (*i.e.* bills the health benefit plan), and a second in which the "healthcare provider" separately submits a "service request" to the co-pay subsidy administrator. The co-pay subsidy administrator then provides "Backstage Support Services:" confirming that the patient is enrolled in the program, paying the "secondary benefit" (the co-pay subsidy) to the pharmacy, and submitting information about the patient's prescription to the "sponsor" (the drug manufacturer):

⁶⁴ *Id.* at Background of the Invention (emphasis added).

⁶⁵ *Id.* at Summary of the Invention.

⁶⁶ *Id.* at Secondary Benefits Provided by Administrator (emphasis added).

**FIG. 4.**

2. TrialCard and PDMI co-administer the Celebrex, Chantix, Effexor XR, Lipitor, and Pristiq co-pay subsidy programs for Pfizer.

189. On information and belief, PDMI and TrialCard co-administer the Effexor XR, Lipitor, Geodon, Pristiq, and Chantix co-pay subsidy programs for Pfizer. PDMI and TrialCard are *not* named as defendants in this action but are unnamed co-conspirators for purposes of RICO and antitrust violations.

190. TrialCard holds certain patents (namely, U.S. Patent Nos. 7,925,531 and 8,055,542) that streamline the administration process for processing co-pay subsidies at the point of sale.

191. PDMI designs, implements, and manages pharmacy benefit programs that align with the business strategies of its clients (*e.g.*, pharmaceutical companies).

192. On information and belief, PDMI has partnered with TrialCard to perform co-pay adjudications, whereby TrialCard's technology is used to initiate the claims process, and claims are then submitted to PDMI under BIN 610020.

a. TrialCard's technology is utilized in the adjudication process.

193. TrialCard advertises that it “provides branded Co-pay card programs that deliver an instant electronic rebate to a patient at the pharmacy, reducing out-of-pocket expense and equalizing tier position for [a manufacturer’s] product.”⁶⁷ The company boasts that its co-pay program “[o]ffsets unfavorable tier/Co-pay position to level [the] playing field for patient out-of-pocket,” and that one of its “client[s] reported [a return on investment] exceeding 600%.”⁶⁸

194. According to TrialCard, its co-pay subsidy cards are “[a]ccepted at all pharmacies” and are “the most accepted card at the pharmacy in the United States.”⁶⁹

195. TrialCard touts that its programs are “innovative, customizable, and reliable,” and that it provides “[f]irst-to-market solutions” for its clients.⁷⁰

196. TrialCard publicizes that it was the “1st to deliver a pharmacy Co-Pay card utilizing the Coordination of Benefit process,” and that its co-pay cards provide pharmaceutical manufacturers with the following benefits: 1) “Certainty that [the] co-pay program achieves [the] brand’s goal of equalizing formulary co-pays”; 2) the ability “to manage coupon utilization versus depending on sales distribution and pull through”; 3) a “favorable co-pay” for the patient “[r]egardless of Tier position”; and 4) “TrialCard® agents” who “champion and facilitate process for the pharmacy and patient.”⁷¹

197. TrialCard also boasts that it was the “1st to require a real-time patient activation enabling collection of patient level information.”⁷² Patients who use TrialCard co-pay savings cards “can activate while standing in line versus dealing with a multiple day delay.”⁷³

⁶⁷ Trial Card CoPay Programs, <http://corpsite.trialcard.com/Pages/CoPayPrograms.aspx> (last visited Mar. 5, 2012).

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

198. TrialCard prides itself on being the “1st to allow programs to limit the amount of benefit an individual can receive across multiple offers,” which has the benefit of “provid[ing] an annual benefit cap at the patient level” for various co-pay subsidy programs.⁷⁴

199. TrialCard holds a patent, filed on March 15, 2002, for a means of processing co-pay subsidies at the point of sale.⁷⁵ This patent describes the processes by which pharmaceutical manufacturers have previously attempted to distribute product samples to patients, and details the inefficiency of these methods:

One cost-reducing approach that pharmaceutical manufacturers have attempted is the distribution of sample vouchers to prescribing physicians, retail pharmacies, and pharmaceutical sales representatives. With this approach, instead of giving drug product samples directly to patients, physicians give the patients vouchers for the drug product samples. The vouchers may then be redeemed at retail pharmacies for the actual drugs. Alternately, the patients may receive cash or credit rebates at the pharmacies.

Another cost-reducing approach that pharmaceutical manufacturers have attempted is the distribution of product samples via mail order. With this approach, pharmaceutical sales representatives provide prescribing physicians with request authorization forms. Physicians then use the forms to authorize deliveries of product samples directly to the physician’s office from third-party pharmaceutical supply warehouses.

These approaches to distributing pharmaceutical product samples have not met with substantial and universal acceptance. All of these approaches lack an effective, efficient and practical system for distributing the trial or sample products to patients and at the same time recording pertinent data, which is easily accessible, relating to prescribing and dispensing the pharmaceutical trial products.⁷⁶

200. To improve efficiency, TrialCard developed an “improved method of dispensing, tracking, and managing pharmaceutical products by communicatively linking prescribers and

⁷⁴ *Id.*

⁷⁵ U.S. Patent No. 7925531 (issued Apr. 12, 2011).

⁷⁶ *Id.* at 27.

pharmacies to a central computing station in such a manner that variable values may be provided to different individuals based on selected variables.”⁷⁷

201. TrialCard explains how the system can be used to process co-pay subsidy programs:

For example, the present invention can be useful in dispensing, tracking and generally managing any type of sample or trial product program such as a pharmaceutical sample program. Further, the method and system of the present invention can be used in product loyalty programs, *co-pay programs where a third party, such as a pharmaceutical company, participates to make a prescription co-payment for the consumer*, patient assistance programs that are sponsored by pharmaceutical companies, and in general is applicable to promoting and advertising goods and services of all types.⁷⁸

202. On its website, TrialCard explains that its “ground-breaking technology” “enables prescription Co-pay cards and coupons to adjust value based on a patient’s insurance coverage. [The] AdjustingValue™ technology maximizes promotional spend for co-pay programs that offer ‘Pay No More Than . . .’ or ‘Save Up To . . .’ savings.”⁷⁹

203. TrialCard’s patent discusses how the co-pay subsidy “media” can be encoded with certain information and can assume the form of a magnetic card that can be read at any pharmacy.

The product trial media **18** can assume various tangible forms. However, in the example illustrated in FIGS. 2A and 2B and discussed herein, the product trial media **18** is in the form of a conventional magnetic card which again is designed to be compatible with a READ-ONLY magnetic reader terminal located at prescriber and pharmacy sites.⁸⁰

⁷⁷ *Id.*

⁷⁸ *Id.* at 36 (emphasis added).

⁷⁹ TrialCard Patents, <http://corpsite.trialcard.com/Pages/Patents.aspx> (last visited Mar. 5, 2012).

⁸⁰ U.S. Patent No. 7,925,531 at 29.

204. These cards help streamline the adjudication process, as a claim can be processed easily after an individual “swipes” his/her card at the pharmacy.

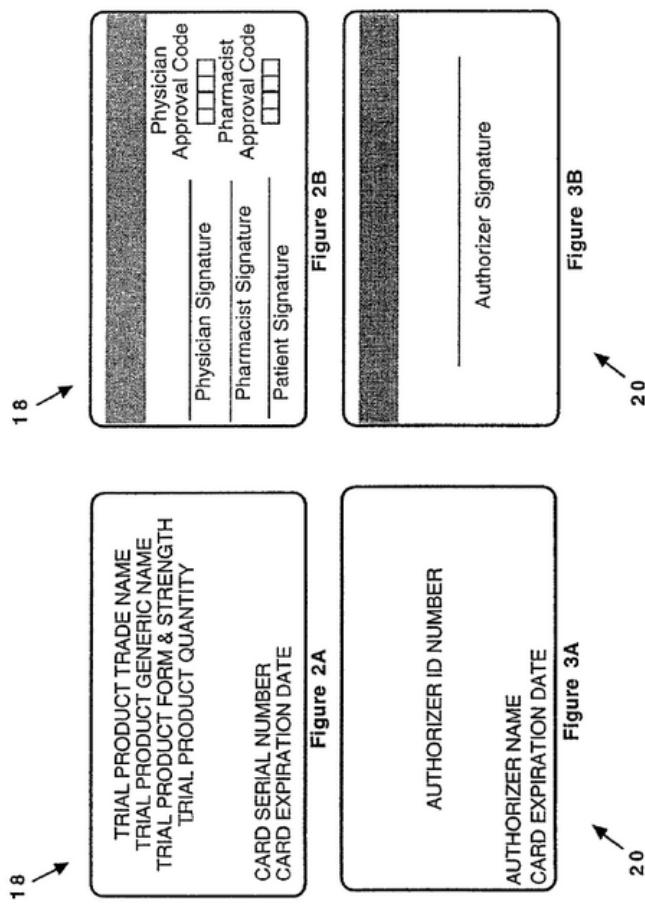


Figure 2 & 3

205. The pharmacist will fill a prescription of any presented media only after undertaking a “validation procedure” to “establish[] that the presented media **1B** is authentic, still within an acceptable date range, has been activated by a prescriber, and has not previously been validated, or if previously validated, still has valid refills available.”⁸¹

⁸¹ *Id.* at 31.

206. TrialCard also holds another patent related to card media, filed on July 21, 2006, which similarly addresses the distribution of pharmaceutical products.⁸²

207. TrialCard submits to PDMI, under BIN 610020, the user information encoded onto the cards for each co-pay program, and PDMI finalizes the adjudication process.

b. PDMI designs the co-pay subsidy programs and processes coordination of benefits claims.

208. PDMI is a claims administrator with a network that includes over 60,000 pharmacies nationwide, including “most chain pharmacies as well as independent pharmacies.”⁸³ Its pharmacy network agreements cover all aspects of the business it supports, including discount and trial cards. PDMI advertises that it provides a “high level of support” to its clients “in the areas of claims processing and benefit design.”⁸⁴

209. PDMI states that it “provides its clients with assistance in benefit plan design based on years of experience processing pharmacy claims. With this knowledge, PDMI has assisted a variety of clients with developing and maintaining their benefits.”⁸⁵

210. PDMI has designed co-pay structures to “accommodate all copay requests, including multi-tiered benefits.” PDMI can implement “[c]opays based on the greater of a dollar amount or percentage of cost basis [and it] has the ability to apply minimum or maximum copays. For example, if the percentage copay (the percentage of the drug cost that is the copay) is greater than the maximum amount, the maximum amount will apply. If the percentage copay is less than the minimum amount, the percentage copay will apply. Maximum and minimum amounts can only be fixed dollar amounts.”⁸⁶

⁸² U.S. Patent No. 8,055,542 (issued Nov. 8, 2011).

⁸³ <http://www.pdmi.com/pharmacy-network-capabilities.htm> (last visited Mar. 5, 2012).

⁸⁴ Benefits of Pharmacy Data Management, <http://www.pdmi.com/benefits.htm> (last visited Mar. 5, 2012).

⁸⁵ *Id.*

⁸⁶ *Id.*

211. PDMI also provides worksheets detailing how claims should be submitted by pharmacies in accordance with the National Council for Prescription Drug Programs' standards. Included on the worksheets are "coordination of benefits" sections, used to establish the order in which health benefit plans pay claims when more than one payor exists.

212. The Celebrex, Chantix, Effexor XR, Lipitor, and Pristiq co-pay card subsidy programs instruct pharmacists to process co-pay card subsidies as a secondary form of insurance and to bill the subsidy amount to PDMI, using BIN number 610020.

H. Health benefit providers do not know, and cannot know, when defendants subsidize their members' co-pays.

213. Health benefit providers are generally aware that drug companies offer co-pay subsidy programs. But health benefit providers do not know, and cannot know, which of the prescriptions that they have paid for have been subsidized. Pharmacists process subsidies as instructed by the defendants and their co-conspirator administrators, and they do not tell health benefit providers or PBMs when a prescription has been subsidized. Defendants, however, possess detailed records of each and every subsidized prescription. The extent of the injury to DC 37, Sergeants, and the classes can easily be determined through discovery of defendants' co-pay subsidy program records.

I. Defendants' co-pay subsidy programs intentionally interfere with the relationship between health benefit providers and their members.

214. By providing undisclosed kickbacks to reduce or eliminate the cost-sharing mechanism in thousands of health insurance contracts for widely used maintenance prescription drugs, defendants unfairly undermine health benefit providers' best attempts to control prescription drug costs. Pharmacy and Therapeutics ("P&T") committees arrive at formulary placement decisions after considerable decision-making, in an effort to address overall prescription drug costs as a burden on the delivery of quality health care. Even small co-pay

subsidies meddle with the cost share balance so carefully struck by P&T committees in formulary tier structures and cost containment provisions in prescription drug benefit plans. Defendants offer such sweeping bribes that they often effectively reduce the co-pay for their branded drugs to *less* than the average co-pay for therapeutic or AB-rated generic alternatives, thereby completely neutralizing health benefit providers' contractual tiered formulary structure.

215. Defendants intend to interfere with health plans' cost-sharing provisions. For example, McKesson's patent (discussed above) specifically contemplates a co-pay subsidy program that absorbs the entire amount of the patient's cost share obligation:

“[A] program could be designed to capture the patient's cost share requirement for a drug as determined by the patient's prescription drug coverage and subsequently provide the patient an additional discount on the final prescription cost. . . . Although fixed discounts may be offered, such as variable discounts which reduce all patient cost share amounts, regardless of individual drug benefit coverage, to a fixed dollar amount.”⁸⁷

216. The co-pay subsidy kickbacks also force other potential short or long-term changes in available prescription drug coverage. Without a means of enabling cost *sharing* (and make no mistake about it, defendants' co-pay subsidy programs disable the ability of plans and their members to agree to effective sharing programs), plans are left to consider wholesale cost *shifting*, under which the benefit provider pays *none* of the cost of a branded drug, and the member pays *all* of the cost, when alternatives to a branded drug exist. At base, defendants have unfairly, deceptively and improperly interfered with health insurance providers' ability to effectively contract for appropriate cost-sharing provisions in insurance contracts.

217. Finally, as described above, and despite defendants fine-print disclaimers to the contrary, the co-pay subsidy kickbacks are an unlawful form of secondary health insurance.

⁸⁷ U.S. Patent No. 7957983, at 11.

J. Defendants' co-pay subsidy programs involve misrepresentations sent via mail and the wires.

1. Defendants could not run their programs without using the mail and wires.

218. Defendants make individuals aware of their respective co-pay subsidy programs through the mail and wires. Defendants advertise their co-pay subsidy programs on the Internet, splashing links across websites devoted to their brand name drugs. Defendants also advertise their programs in magazines and network television: as an example, in October 2011, Pfizer advertised its Lipitor \$4 Co-Pay Card program in a two and a half page magazine advertisement (that ran in *People* and other magazines) and commercials that ran on major television networks.

219. Defendants have individuals sign up for their programs via the wires. Most patients sign up to participate in the programs online, filling out information that is transmitted to the defendants via the Internet.

220. Defendants send the physical co-pay cards to individuals, doctors, and pharmacies via the mail.

221. Co-conspirator McKesson's patent for methods of administrating these co-pay subsidy programs expressly contemplates pharmacies, co-pay subsidy program administrators, and manufacturers of sponsored drugs communicating through "one or more data networks, such as a local area network (LAN), a metropolitan area network (MAN) and/or a wide area network (WAN) (e.g. Internet) and . . . one or more voice networks, such as a public-switched telephone network (PSTN)."⁸⁸

⁸⁸ U.S. Patent No. 7,957,983.

222. TrialCard envisions activating co-pay cards “via the World Wide Web, calling a toll-free 8xx number, responding with a business reply card, or communicating with the central database through a terminal, such as a magnetic card reader.”⁸⁹

223. The co-pay subsidy enterprises do, in fact, use the mail and wires to implement these programs: defendants and their co-conspirators use the wires to have the pharmacy contact the administrator about the number of subsidized prescriptions filled and the amount subsidized for each prescription, and the administrator in turn contacts the manufacturer and communicates the subsidy information to the manufacturer.

224. Defendants also use the mail and wires to send money to the administrator, and the administrator sends money to the pharmacy to effectuate reconciliation and reimburse the pharmacy for recognizing the co-pay subsidies.

225. These communications between pharmacies, the administrators, and the defendants occur tens of thousands of times per year. Defendants and their co-conspirators possess information about the specific dates of transactions, which defendants have withheld from health benefit plans.

2. Defendants convey two distinct misrepresentations via the mail and wires.

226. Defendants and their co-conspirators make misrepresentations via the wires at the time of the point of sale transaction — that is, when the member presents the co-pay card at the pharmacy — when, as instructed by the defendants, the pharmacist electronically charges the health benefit provider the full benchmark price without accounting for the existence of co-pay subsidies. These transactions necessarily involve the use of the wires.

⁸⁹ U.S. Patent No. 7925531 at 14.

227. Defendants make additional misrepresentations via the mail and wires when defendants report benchmark prices to reporting agencies while failing to account for the routine waiver of co-pays. These transactions necessarily involve the use of the mail and wires.

VI. CLASS ALLEGATIONS

228. Plaintiffs bring this action pursuant to Federal Rule of Civil Procedure 23, on behalf of themselves and eight national classes (one for each of the eight programs discussed above) defined as:

All entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of a co-pay subsidy drug prescribed to natural persons covered by such contract, policy, or plan, and who paid for at least one prescription for Celebrex, Chantix, Effexor XR, Enbrel, Geodon, Lipitor, Pristiq, or Sensipar that was subsidized by defendants' co-pay subsidy program(s).

229. The class periods run from when defendants started offering the co-pay subsidy programs until defendants stop offering the programs. The precise periods will be identified through discovery.

230. Excluded from the classes are (i) defendants, defendants' legal representatives, officers, directors, assignees, predecessors, and successors, (ii) federal and state governmental entities administering prescription drug programs under Medicare, Medicaid, and or other federally or state-sponsored programs, and (iii) counsel for plaintiffs and the classes' self-funded health benefit plans (if any).

231. All class members have suffered, and will continue to suffer, harm and damages as a result of defendants' unlawful and wrongful conduct.

232. Defendants' co-pay subsidies are specifically targeted to undermine the cost share provisions in those contracts.

233. Class members can be precisely determined from defendants' records, the records of the administrators of defendants' co-pay subsidy programs, and pharmacy records. Members of the classes themselves are unable to identify the subsidized prescriptions. However, defendants possess information about the subsidized prescriptions, including the name and specific identifying information about each participating member and the pharmacy where the prescription was filled. The pharmacy has a record of both the amount of subsidy and the individual's health plan. The administrators also have this information, as well as the accumulated results of the programs through all pharmacies. No uninjured parties will be included within the classes because each member can be determined with specificity, based on actual transactional data.

234. The fact of injury or damages to each class member can also be reasonably estimated from existing data. Aggregate damages to the classes as a whole can reasonably be estimated from existing data, and commonly-used mechanisms by which to allocate that award amongst class members exist.

235. The classes consist of thousands of private health benefit providers. These providers are geographically dispersed throughout the United States. The disposition of all claims in a single action will substantially benefit all parties and the Court.

236. Plaintiffs DC 37 and Sergeants are the proposed class representatives.⁹⁰

237. The claims of DC 37 and Sergeants are typical of the claims of the classes. Both DC 37 and Sergeants purchased drugs on behalf of their members whose cost share obligations were subsidized by defendants. DC 37 and Sergeants, like all class members, paid for too many co-pay subsidy drug prescriptions as a result of defendants' subsidies. DC 37 and Sergeants will

⁹⁰ DC 37 is the proposed class representative for all classes described herein. Sergeants is a proposed class representative for the Celebrex and Lipitor classes only.

fairly and adequately protect the interests of the classes. DC 37 and Sergeants have retained counsel with substantial experience prosecuting nationwide third party payor class actions. DC 37, Sergeants, and their counsel are committed to vigorously prosecuting this action on behalf of the classes and have the financial resources necessary to do so.

238. The factual and legal issues regarding defendants' alleged misconduct are common to all class members and represent a common thread of misconduct resulting in injury to DC 37, Sergeants, and the classes. Common questions of law and fact include:

- a. Whether defendants engaged in a course of conduct that improperly increased plaintiffs' and other class members' drug costs;
- b. Whether defendants engaged in kickback schemes to increase plaintiffs' and other class members' drug costs;
- c. Whether defendants engaged in a pattern of deceptive and/or fraudulent activity intended to defraud plaintiffs and other members of the classes;
- d. Whether defendants formed an enterprise for the purpose of effectuating its fraudulent schemes;
- e. Whether defendants used the U.S. mails and interstate wire facilities and commerce to carry out this fraudulent schemes;
- f. Whether defendants engaged in conduct that violated the federal racketeering laws as alleged herein;
- g. Whether defendants engaged in conduct that violated federal antitrust laws as alleged herein;

- h. Whether plaintiffs and the other members of the classes were injured by the conduct of defendants and, if so, the appropriate class-wide measure of damages; and
- i. Whether plaintiffs and the other members of the classes are entitled to injunctive relief.

239. Prosecution of separate actions by individual class members would create the risk of inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for defendants.

240. Defendants have acted on grounds generally applicable to all class members in that defendants' anticompetitive and fraudulent actions uniformly impacted all class members. Accordingly, injunctive relief is necessary to protect all class members from further injury.

241. Plaintiffs know of no difficulty that would prevent this case from being maintained as a class action. A class action is the superior method for fairly and efficiently adjudicating this controversy. The cost of litigating a single action would prevent most class members from bringing suit individually. Class action treatment will, among other things, allow a large number of similarly situated entities to prosecute their common claims in a single forum, thus avoiding the unnecessary duplication of resources that numerous individual actions would require. Moreover, class action treatment allows injured payors, including smaller plans with limited means, to seek redress on claims that might be impracticable to pursue individually. Thus, absent a class action, there would be no remedy at law for thousands of injured entities. And absent a class action, there would be no mechanism for imposing uniform equitable injunctive relief to the classes as a whole.

VII. CAUSES OF ACTION

COUNTS ONE THROUGH EIGHT SUBSTANTIVE RICO VIOLATION (18 U.S.C. § 1962(c))

242. These Counts allege substantive violations of RICO (as provided in 18 U.S.C. § 1962(c)), relating to the co-pay subsidy programs described above, and are asserted against defendants on behalf of plaintiffs and the classes.

243. COUNT ONE is asserted against defendant Pfizer for the Celebrex co-pay subsidy program. The Celebrex co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and unnamed co-conspirators TrialCard and PDMI.

244. COUNT TWO is asserted against defendant Pfizer for the Chantix co-pay subsidy program. The Chantix co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and unnamed co-conspirators TrialCard and PDMI.

245. COUNT THREE is asserted against defendant Pfizer for the Effexor XR co-pay subsidy program. The Effexor XR co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and unnamed co-conspirators TrialCard and PDMI.

246. COUNT FOUR is asserted against defendants Amgen and Pfizer for the Enbrel co-pay subsidy program. The Enbrel co-pay subsidy enterprise is an association-in-fact comprised of defendant Amgen, defendant Pfizer, and unnamed co-conspirator McKesson.

247. COUNT FIVE is asserted against defendant Pfizer for the Geodon co-pay subsidy program. The Geodon co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and unnamed co-conspirators TrialCard and PDMI.

248. COUNT SIX is asserted against defendant Pfizer for the Lipitor co-pay subsidy programs. The Lipitor co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and unnamed co-conspirators TrialCard and PDMI.

249. COUNT SEVEN is asserted against defendant Pfizer for the Pristiq co-pay subsidy program. The Pristiq co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and unnamed co-conspirators TrialCard and PDMI.

250. COUNT EIGHT is asserted against defendant Amgen for the Sensipar co-pay subsidy program. The Sensipar co-pay subsidy enterprise is an association-in-fact comprised of defendant Amgen and unnamed co-conspirator McKesson.

251. These enterprises are referred to collectively as the “co-pay subsidy enterprises.” The drugs Celebrex, Chantix, Effexor XR, Enbrel, Geodon, Lipitor, Pristiq, and Sensipar, are referred to collectively as the “subsidized drugs.”

252. Plaintiffs, members of the classes, defendants, and the unnamed co-conspirators are all “persons” as defined by 18 U.S.C. § 1961(3).

A. Each defendant and their respective co-conspirators formed association-in-fact RICO enterprises.

253. For purposes of this claim, the RICO co-pay subsidy enterprises alleged herein are associations-in-fact within the meaning of 18 U.S.C. § 1961(4). Each defendant and its co-conspirator administrators, including their directors, employees, and agents, formed association-in-fact enterprises. These co-pay subsidy enterprises are each an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purpose of maximizing sales of subsidized drugs by unlawfully interfering with cost-sharing provisions.

254. Within each co-pay subsidy enterprise there are contractual relationships, financial ties, and continuing coordination activities between defendants and their co-conspirator administrators.

255. On information or belief, members of each co-pay subsidy enterprise have communicated repeatedly over the course of several years to carry out their common purposes, and have entered into, monitored, and enforced contractual and/or agency arrangements regarding payment and the delivery of services. Defendants hired the administrators to carry out the program.

B. Each co-pay subsidy enterprise engaged in and affected interstate commerce.

256. Each co-pay subsidy enterprise engaged in and affected interstate commerce because it involved thousands of transactions at hundreds of pharmacies all over the country and is attendant to defendants marketing, distribution, and sale of the subsidized drugs across state boundaries and throughout the United States.

257. During the class periods, the illegal conduct and wrongful practices carried out by members of each co-pay subsidy enterprise (including defendants and the administrators) were effectuated by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products, and funds through the United States mails and interstate wire facilities. In particular, administrators transmit pharmacy data to defendants and defendants transmitted funds to the administrators, who transmitted funds to the pharmacies.

C. Each defendant associated with its respective co-pay subsidy enterprises.

258. The nature of the co-pay subsidy schemes required each defendant to form and participate in enterprises. Defendants hired their co-conspirator administrators and monitored and enforced this contractual arrangement regarding payment and the delivery of services. Each of these actions was necessary to, or helpful in, each co-pay subsidy enterprise's ability to carry out its goal of interfering with plaintiffs and class members' cost-sharing provisions and causing

plaintiffs and class members to be charged an inflated reimbursement rate for subsidized prescriptions.

D. The co-pay subsidy enterprises engaged in a pattern of racketeering activity.

259. Defendants conducted and participated in the affairs of the co-pay subsidy enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341 (mail fraud) and 18 U.S.C. § 1343 (wire fraud).

1. The co-pay subsidy enterprises engaged in schemes to defraud.

260. The co-pay subsidy enterprises engaged in intentional schemes to defraud plaintiffs and the classes by interfering with their cost-sharing provisions, causing them to pay for prescriptions of the subsidized drugs that they would not otherwise have paid for, and causing them to pay an inflated rate for each subsidized prescription. These transactions necessarily involve the use of the wires.

261. The co-pay subsidy enterprises engaged in separate but related intentional schemes to defraud plaintiffs and the classes by causing misrepresentations to be made via the wires at the time of the point of sale transaction — that is, when the member presents the co-pay card at the pharmacy — when as instructed by the defendants, the pharmacist electronically charges the health benefit provider the full benchmark price without accounting for the existence of co-pay subsidies. These transactions necessarily involve the use of the wires.

262. The co-pay subsidy enterprises engaged in separate but related intentional schemes to defraud plaintiffs and the classes by reporting benchmark prices to reporting agencies while failing to account for the routine waiver of co-pays. These transactions necessarily involve the use of the mail and wires.

263. Defendants knew that entities like plaintiffs and members of the classes have cost-sharing programs to reduce the use of brand drugs by their plan members. The purpose and

intent of defendants' co-pay subsidy scheme was to overcome such restrictions on brand drug purchases and to cause plaintiffs and the classes to pay for more prescriptions for the subsidized drugs at artificially inflated prices.

2. The co-pay subsidy enterprise used interstate communications systems to carry out these schemes.

264. The nature of these schemes necessarily required members of each co-pay subsidy enterprise to communicate directly and frequently by the U.S. mails and interstate wire facilities.

265. Many of the precise dates of the co-pay subsidy enterprises' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to defendants' records. An essential part of the successful operation of the co-pay subsidy enterprises was defendants' ability to conceal the use of subsidies from DC 37, Sergeants, and the classes at the point of sale.

266. During the class periods, defendants exerted control over the co-pay subsidy enterprises, and in violation of § 1962(c) of RICO, they conducted and participated in the conduct of the affairs of the co-pay subsidy enterprises, directly or indirectly, in the following ways:

- i. Defendants conceived of and implemented the unlawful co-pay subsidy programs;
- ii. Defendants directly controlled the creation and distribution of marketing, sales, and other materials used to inform patients and physicians about the unlawful co-pay subsidy programs;
- iii. Defendants set the terms of the programs, including eligibility criteria, amount of subsidy, and number of subsidies;

- iv. Defendants caused the administrators to administer the programs without informing health benefit plans about the subsidies; and
- v. Defendants instructed and caused pharmacies to charge health benefit plans an inflated reimbursement rate for subsidized prescriptions by instructing the pharmacy to process the co-pay card as though it were a form of secondary insurance.

267. Defendants' pattern of racketeering likely involved tens of thousands of separate instances of use of the U.S. mails or interstate wire facilities to carry out the unlawful co-pay subsidies. Each of these fraudulent mailings and interstate wire transmissions and/or each transaction to charge health benefit plans an inflated reimbursement rate for subsidized prescriptions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). These violations constitute a "pattern" of racketeering activity within the meaning of 18 U.S.C. § 1961(5) in which defendants intended to defraud plaintiffs and members of the classes.

E. The unlawful activity proximately injured plaintiffs and the classes.

268. Defendants' participation in the affairs of the co-pay subsidy enterprises through a pattern of racketeering activity has directly and proximately caused DC 37, Sergeants, and members of the classes to be injured in their business or property. Plaintiffs, members of the classes, and others reasonably relied upon a belief that their members were paying their share of prescription drug costs (as determined by the cost-sharing provisions of their particular health plan) and that pharmacies were reporting and charging a reimbursement rate that accurately reflected the price defendants actually charged for the subsidized drugs .

269. Defendants profited directly from the co-pay subsidy schemes in the form of increased sales of the subsidized drugs that plaintiffs and the classes would not otherwise have purchased but for defendants' interference with their cost-sharing programs. As a direct and

proximate result of defendants' overt acts and or predicate acts in furtherance of violating 18 U.S.C. § 1962(c), plaintiffs and the classes have been and are continuing to be injured in their business or property.

270. Plaintiffs and members of the classes were injured in their property by reason of these violations because plaintiffs and members of the classes have paid for an increased number of prescriptions for the subsidized drugs as a result of the co-pay subsidy enterprises' substantive RICO violations. By reason of the unlawful acts engaged in by each co-pay subsidy enterprise, plaintiffs and the classes have suffered ascertainable loss and damages. These injuries were directly and proximately caused by defendants' racketeering activity.

271. Under § 1964(c) of RICO, defendants are liable to DC 37, Sergeants, and members of the classes for three times the damages sustained, plus the cost of bringing suit and reasonable attorneys' fees.

**COUNTS NINE THROUGH SIXTEEN
CONSPIRACY TO VIOLATE RICO
(18 U.S.C. § 1962(d))**

272. These Counts allege conspiracies to violate RICO (as provided in 18 U.S.C. § 1962(d)), relating to the co-pay subsidy programs described above, and is asserted against defendants on behalf of DC 37, Sergeants, and the classes.

273. COUNT NINE is asserted against defendant Pfizer for the Celebrex co-pay subsidy program. The Celebrex co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and unnamed co-conspirators TrialCard and PDMI.

274. COUNT TEN is asserted against defendant Pfizer for the Chantix co-pay subsidy program. The Chantix co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and unnamed co-conspirators TrialCard and PDMI.

275. COUNT ELEVEN is asserted against defendant Pfizer for the Effexor XR co-pay subsidy program. The Effexor XR co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and co-conspirators TrialCard and PDMI.

276. COUNT TWELVE is asserted against defendants Amgen and Pfizer for the Enbrel co-pay subsidy program. The Enbrel co-pay subsidy enterprise is an association-in-fact comprised of defendant Amgen, defendant Pfizer, and unnamed co-conspirator McKesson.

277. COUNT THIRTEEN is asserted against defendant Pfizer for the Geodon co-pay subsidy program. The Geodon co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and unnamed co-conspirator unnamed co-conspirators TrialCard and PDMI.

278. COUNT FOURTEEN is asserted against defendant Pfizer for the Lipitor co-pay subsidy programs. The Lipitor co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and unnamed co-conspirators TrialCard and PDMI.

279. COUNT FIFTEEN is asserted against defendant Pfizer for the Pristiq co-pay subsidy program. The Pristiq co-pay subsidy enterprise is an association-in-fact comprised of defendant Pfizer and unnamed co-conspirators TrialCard and PDMI.

280. COUNT SIXTEEN is asserted against defendant Amgen for the Sensipar co-pay subsidy program. The Sensipar co-pay subsidy enterprise is an association-in-fact comprised of defendant Amgen and unnamed co-conspirator McKesson.

281. These enterprises are referred to collectively as the “co-pay subsidy enterprises.” The drugs Celebrex, Chantix, Effexor XR, Enbrel, Geodon, Lipitor, Pristiq, and Sensipar are referred to collectively as the “subsidized drugs.”

282. Section 1962(d) of RICO provides that it “shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section.” Defendants

have violated Section 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of their ongoing conspiracies was to conduct or participate in, directly or indirectly, the conduct of the affairs of the co-pay subsidy enterprises through a pattern of racketeering activity.

283. Defendants adopted the goal of furthering or facilitating the criminal endeavor of the co-pay subsidy enterprises minimally by agreeing to facilitate some of the acts leading to the substantive offense, and directly engaging engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracies, as described above.

284. Defendants not only agreed to the objectives of each 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity.

285. By hiring the administrators to carry out the co-pay subsidy schemes, defendants minimally engaged in overt acts in furtherance of the schemes as well as predicate violations of mail or wire fraud. As a direct and proximate result of defendants' overt acts and/or predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), plaintiffs and members of the classes have been and are continuing to be injured in their business or property.

286. Plaintiffs and members of the classes were injured in their property by reason of these violations in that plaintiffs and members of the classes have paid for an increased number of prescriptions for the subsidized drugs as a result of the co-pay subsidy enterprises' conspiracies to violate 18 U.S.C. § 1962(c).

287. By reason of the unlawful acts engaged in by each co-pay subsidy enterprise, plaintiffs and the classes have suffered ascertainable loss and damages. These injuries were directly and proximately caused by defendants' racketeering activity.

288. By virtue of these violations of 18 U.S.C. § 1962(d), defendants are liable to DC 37, Sergeants, and the classes for three times the damages sustained, plus the cost of this suit and reasonable attorneys' fees.

**COUNTS SEVENTEEN THROUGH TWENTY-FOUR
COMMERCIAL BRIBERY IN VIOLATION OF ROBINSON-PATMAN ACT
(15 U.S.C. § 13 (c))**

289. These Counts allege commercial bribery in violation of the Robinson-Patman Act (as provided in 15 U.S.C. § 13 (c)), relating to the co-pay subsidy programs described above, and is asserted against defendants Amgen and Pfizer on behalf of plaintiffs DC 37, Sergeants, and the classes.

290. COUNT SEVENTEEN is asserted against defendant Pfizer for the Celebrex co-pay subsidy program.

291. COUNT EIGHTEEN is asserted against defendant Pfizer for the Chantix co-pay subsidy program.

292. COUNT NINETEEN is asserted against defendant Pfizer for the Effexor XR co-pay subsidy program.

293. COUNT TWENTY is asserted against defendants Amgen and Pfizer for the Enbrel co-pay subsidy program.

294. COUNT TWENTY-ONE is asserted against defendant Pfizer for the Geodon co-pay subsidy program.

295. COUNT TWENTY-TWO is asserted against defendant Pfizer for the Lipitor co-pay subsidy programs.

296. COUNT TWENTY-THREE is asserted against defendant Pfizer for the Pristiq co-pay subsidy program.

297. COUNT TWENTY-FOUR is asserted against defendant Amgen for the Sensipar co-pay subsidy program.

298. These programs are referred to collectively as the “co-pay subsidy programs.” The drugs Celebrex, Chantix, Effexor XR, Enbrel, Geodon, Lipitor, Pristiq, and Sensipar are referred to collectively as the “subsidized drugs.”

299. Section 2(c) of the Robinson-Patman Act prohibits the payments by drug manufacturers to, or on behalf of individual insureds to eliminate or reduce their personal obligations under their prescription drug plans’ cost-sharing plans. The relevant part of the statute makes it unlawful for any person engaged in commerce to:

(1) pay (or receive)-

- (a) anything of value as a commission, brokerage, or other compensation, or
- (b) by allowance or discount in lieu of brokerage, *except* for services rendered in connection with a sale or purchase of goods,

(2) when the payment is made to (or by)

- (a) the other party to the transaction, or
- (b) an agent, representative or other intermediary where the intermediary is
 - (i) acting for or in behalf of, or
 - (ii) subject to the direct or indirect control of
 - (iii) any party to the transaction other than the person by whom the compensation is paid.⁹¹

300. Generally, these provisions of the Robinson-Patman Act bar commercial bribery, *i.e.*, they prohibit a person from paying off fiduciaries, agents or other intermediaries who control purchasing decisions to be paid for by another. Here, each defendant is a “person” making

⁹¹ 15 U.S.C. §13(c).

payment of something of value: defendants pay individual insureds to choose a subsidized drug that is paid for by the individual's health benefit provider. Paying individuals who receive prescription drug benefits pursuant to plans offered by private health benefit providers plans qualifies as a violation of Section 2(c) of the Robinson-Patman Act because the subsides are "anything of value" which are both (i) paid as "compensation" for purchasing the branded drugs, and (ii) as a "discount in lieu of brokerage."

301. Individual insureds who accept rebates under defendants' co-pay subsidy programs qualify as "agent[s], representative[s] [and] "other intermediar[ies]" because, pursuant to the terms of their agreements with their health benefit providers, they both (i) act on behalf of their health benefit providers in having substantial control in the choice of which medications will be paid for by the health benefit providers and, (ii) under the terms of their agreements with their health benefit providers, act subject to their health benefit providers' direct and indirect control in seeking payment for the selected medication through the terms of their plans. But members do not know these co-pay subsidies are bribes.

302. Defendants offer these co-payment subsidies to privately-insured plan members in order to capture the large payments by private health benefit providers that accompany the relatively modest co-payments made by the individual members. By drastically reducing or eliminating the increased cost-sharing obligation, defendants increase sales of subsidized drugs to the detriment of health benefit plans. Health benefit providers (including DC 37 and Sergeants) invest a great deal of actuarial resources to provide incentives for their members to choose less expensive prescription drug therapy that works as well as pricier drugs. Defendants' co-pay subsidy programs provide illegal inducements to members to choose more expensive

drugs to the detriment of prescription drug plans provided by DC 37, Sergeants, and members of the classes.

303. As a result, defendants' co-pay subsidy programs result in injury to DC 37, Sergeants, and the classes because the payments result in more purchases of subsidized drugs by plaintiffs and the classes than would have been made absent the illegal inducements.

VIII. DEMAND FOR JUDGMENT

304. WHEREFORE, plaintiffs DC 37 and Sergeants, on behalf of themselves and the proposed classes, respectfully request that the Court:

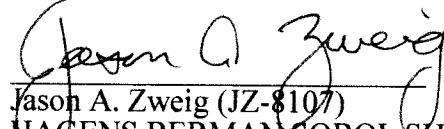
- A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the classes, and declare plaintiffs DC 37 and Sergeants the class representatives;
- B. Enter judgment against defendants in favor of DC 37, Sergeants, and the classes;
- C. Adjudge and decree the acts alleged herein to be unlawful;
- D. Award the classes damages in an amount to be determined at trial;
- E. Award the classes threefold damages pursuant to 18 U.S.C. § 1964(c) and 15 U.S.C. § 15(a);
- F. Award plaintiffs and the classes their costs of suit, including reasonable attorneys' fees as provided by law;
- G. Enjoin defendants from offering these or similar co-pay subsidy programs; and
- H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by defendants' unlawful conduct as the Court deems just.

IX. JURY DEMAND

305. Pursuant to Fed. Civ. P. 38, plaintiffs, on behalf of themselves and the proposed classes, demand a trial by jury on all issues so triable.

Dated: March 27, 2012

Respectfully submitted,



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